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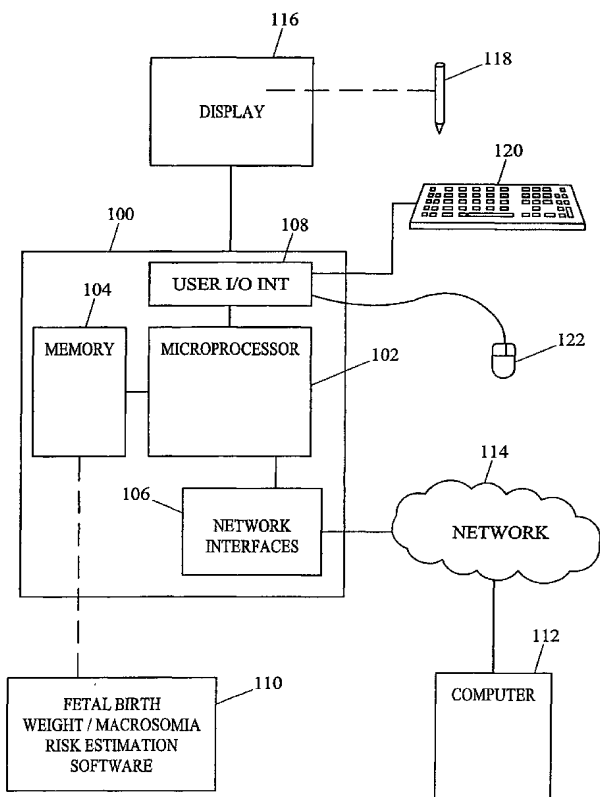
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(54) Title: METHODS, SYSTEMS, AND COMPUTER PROGRAM PRODUCTS FOR ESTIMATING FETAL WEIGHT AT BIRTH AND RISK OF MACROSOMIA

(57) Abstract: Methods and systems for estimating fetal weight at birth and risk of macrosomia are disclosed. Information regarding maternal characteristics and ultrasound measurements are obtained for the fetus. A computer program selects the most accurate equation from a hierarchy of birth weight/risk of macrosomia estimation equations based on the available information. Program outputs include estimated birth weight, risk of macrosomia, and confidence intervals.



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Description

METHODS, SYSTEMS, AND COMPUTER PROGRAM PRODUCTS FOR
ESTIMATING FETAL WEIGHT AT BIRTH AND RISK OF MACROSOMIA

Related Applications

5 This application claims the benefit of U.S. Patent Application Serial No. 10/273,201, filed October 17, 2002, the disclosure of which is incorporated herein be reference in its entirety.

Technical Field

The present invention relates to methods, systems, and computer program products for estimating fetal weight at birth and risk of macrosomia. More particularly, the present invention relates to methods, systems, and computer program products for estimating fetal weight at birth and risk of macrosomia using a hierarchy of equations based on maternal characteristics and fetal ultrasound measurements.

15 Related Art

Obstetricians have been searching for a method to successfully predict birth weight for hundreds of years. This motivation arises because fetuses with both low and high birth weights are at increased risk for newborn complications during the intrapartum and postnatal periods. The complications associated with the delivery of excessively large fetuses include prolonged labor, shoulder dystocia, brachial plexus injury, bony injuries, and intrapartum asphyxia, as well as maternal risks of birth canal and pelvic floor injuries and postpartum hemorrhage. In addition, the occurrence of cephalopelvic disproportion is more prevalent as fetal size increases, contributing to both an increased rate of

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operative vaginal delivery and of cesarean section for macrosomic fetuses as compared with fetuses of normal weight. Thus, there is an increase not only in the morbidity and mortality associated with the birth of macrosomic fetuses, but also a significant increase in both the direct and indirect costs associated with
5 their birth and lifetime care.

If fetal weight could be known with reasonable certainty in advance of delivery, the timing and mode of delivery for women carrying macrosomic fetuses could be modified to improve newborn and maternal outcomes. The problem, until now, has been appropriately identifying abnormally grown
10 fetuses *in utero*, so that modifications to the patient's treatment and delivery plan could be instituted in advance of labor. Because of this, there is significant clinical utility to having a readily available tool to reliably estimate fetal weight before delivery.

Several approaches to prospective birth weight prediction have been
15 attempted. For centuries, simply "feeling" the size of a fetus through the maternal abdominal and uterine walls was the only tool that was available. The predictive accuracy of such tactile assessment of fetal size is suboptimal, with its overall accuracy ranging from ± 7.5 -19.8% of actual birth weight. During the past quarter century, this technique has gradually been supplanted by the
20 method of ultrasonographic fetal biometry. The assumption underlying this change has been that fetal biometric assessments would yield superior estimates of birth weight because the multiple fetal measurements obtained via sonography are quantitative in nature and less "subjective" than the information

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obtained by clinical means. This assumption presupposes that the sonographic measurements of multiple linear and planar dimensions of the fetus provide sufficient parametric information to allow for accurate algorithmic reconstruction of the three-dimensional fetal volume of varying tissue density. Consistent with
5 these beliefs, much effort has been expended to generate best-fit fetal biometric algorithms that can make birth weight predictions based on obstetrical sonographic measurements alone. As such, the ultrasonographic technique represents the newest and most technologically sophisticated method of making fetal weight estimations. Although obstetrical
10 ultrasonography has proven to be a boon as a tool to detect fetal anomalies, position, amniotic fluid volume and placental location, standard sonographic fetal biometric modeling has been an unfortunate failure with regard to predicting fetal weight. Its predictive accuracy has ranged from $\pm 10.7\%$ - 15.6% of actual term birth weight, and it has never approached the level of accuracy
15 required to make the method useful for making clinical decisions regarding optimal patient management.

Accordingly, there exists a need for improved methods and systems for estimating fetal weight at birth and risk of fetal macrosomia.

Description of the Invention

20 The present invention includes improved methods and systems for estimating fetal weight at birth and risk of macrosomia. The present invention may be implemented as a computer program that obtains information from a user and automatically estimates fetal birth weight and/or risk of macrosomia

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based on information provided by the user. As used herein, the term "macrosomia" refers to the condition of a fetus being born with a weight at birth that is greater than a predetermined value. The predetermined value may be based on accepted medical definitions and is preferably programmable by the user. The information used to estimate fetal weight and/or risk of macrosomia includes information regarding maternal characteristics and fetal ultrasound measurements. A user is presented with a questionnaire requesting information regarding maternal characteristics and fetal ultrasound measurements. The responses are input into fetal birth weight/macrosomia risk estimation software. The software runs through a series of logical steps that calculates fetal weight and/or risk of macrosomia based on the available information. More particularly, the software selects the most accurate equation from a uniquely devised set of equations that are empirically derived using statistical methods and multiple sets of proprietary data based on available information about the mother and/or fetal ultrasound measurements. The fetal birth weight/macrosomia risk estimation software outputs one or more numbers indicative of estimated fetal birth weight, risk of macrosomia, and confidence intervals associated therewith. Because the present invention calculates fetal weight at birth and risk of macrosomia by selecting the most accurate prediction equation for the available information, increased accuracy in predicting fetal weight at birth and risk of macrosomia is achieved. In addition, because the present invention allows for the calculation of fetal weight at birth and/or risk of macrosomia up to three months before the actual date of

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delivery, it allows both mothers and obstetrical practitioners time and flexibility in planning the timing and mode of delivery, so as to minimize the ultimate size of fetuses that are projected to be overgrown at particular junctures of gestation, and to minimize the risks of adverse outcomes associated with the
5 delivery process for both these fetuses that are destined to be overgrown and their mothers. As a result, fetal injuries and injuries to the mother can be reduced.

Accordingly, it is an object of the invention to provide improved methods and systems for estimating fetal birth weight.

10 It is yet another object of the invention to provide improved methods and systems for estimating risk of fetal macrosomia.

Some of the objects of the invention having been stated hereinabove, and which are addressed in whole or in part by the present invention, other objects will become evident as the description proceeds when taken in
15 connection with the accompanying drawings as best described hereinbelow.

Brief Description of the Drawings

Preferred embodiments of the invention will now be explained with reference to the accompanying drawings of which:

Figure 1 is a block diagram of an exemplary operating environment for
20 the methods and systems for estimating fetal weight at birth and risk of macrosomia according to an embodiment of the present invention;

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Figure 2 is a flow chart illustrating the overall steps for predicting fetal weight at birth and risk of macrosomia according to an embodiment of the present invention;

Figures 3A-3G are flow charts illustrating exemplary steps for estimating fetal weight at birth according to an embodiment of the present invention; and

Figures 4A and 4B illustrate exemplary steps for estimating risk of fetal macrosomia according to an embodiment of the present invention.

Detailed Description of the Invention

The methods and systems of the invention for estimating fetal weight at birth and risk of macrosomia may be implemented in computer software designed to execute on any suitable computing platform, such as a personal computer, a hand held computer, a laptop computer, or a computer associated with an ultrasound device. Figure 1 illustrates an exemplary operating environment for the fetal birth weight/macrosomia risk estimation software according to an embodiment of the present invention. Referring to Figure 1, a computer **100** includes a microprocessor **102**, memory **104**, network interfaces **106**, and user I/O interfaces **108**. Microprocessor **102** may be any suitable microprocessor for executing stored instructions. An example of a microprocessor suitable for use with embodiments of the present invention is any of the Pentium family of processors available from Intel Corporation. A memory **104** stores instructions to be executed by microprocessor **102**. In the illustrated example, memory **104** may store fetal birth weight/macrosomia risk estimation software **110**.

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Network interfaces **106** may allow computer **100** to communicate with one or more other computers **112** over network **114**. For example, computer **100** may include web server software and computer **112** may include web client software. If computer **100** functions as a server, computer **100** may collect
5 information from users via computer **112**, calculate fetal birth weight and risk of macrosomia, and output the birth weight and risk estimate to computer **112** via network **114**.

User I/O interface **108** manages communications with various user interface devices, such as display **116**, pen **118**, keyboard **120**, and mouse
10 **122**. For example, if computer **100** is a desktop or laptop personal computer, computer **100** may receive input from a user via input devices **120** and **122** and display output to the user via display **116**. If computer **100** is a hand held device, computer **100** may receive input from the user via pen **118** and display **116** and display output to the user via display **116**.

15 Figure 2 is a flow chart illustrating the overall steps performed by fetal birth weight/macrosomia risk estimation software **110** illustrated in Figure 1. Referring to Figure 2, in step **ST1**, fetal birth weight/macrosomia risk estimation software **110** obtains information regarding maternal characteristics for a fetus for which birth weight and risk of macrosomia is to be predicted. In step **ST2**,
20 fetal birth weight/macrosomia risk estimation software **110** obtains information regarding fetal ultrasonographic measurements that may be available for a fetus for which birth weight and risk of macrosomia is to be predicted. Steps **ST1** and **ST2** may be performed using any of the input devices illustrated in

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Figure 1. A detailed explanation of exemplary characteristics and measurements that may be obtained from a user will be explained below.

In step **ST3**, fetal birth weight/macrosomia risk estimation software **110** estimates fetal birth weight based on information obtained in steps **ST1** and **ST2**. The estimation step involves selecting a fetal birth weight calculation equation from a hierarchy of stored equations based on available information. For example, if information regarding maternal characteristics is available but no ultrasound information is available, fetal birth weight/macrosomia risk estimation software **110** uses an equation that uses only maternal characteristics. Alternatively, if both maternal characteristics and ultrasound measurements are available, fetal birth weight/macrosomia risk estimation software **110** uses both maternal characteristics and ultrasound measurements to estimate fetal birth weight and/or risk of macrosomia. An exemplary hierarchy of equations for estimating fetal birth weight and macrosomic risk will be described in detail below.

In step **ST4**, fetal birth weight/macrosomia risk estimation software **110** outputs results to the user along with confidence intervals for the results. For fetal birth weight, the output may be the estimated weight of the fetus in grams along with a confidence interval for the calculation. For risk of macrosomia, the output may be a test string indicating the presence or absence of macrosomia and/or a percentage indicating the risk of macrosomia at the time of birth.

In order to perform steps **ST1** and **ST2** illustrated in Figure 1, the user is preferably presented with a questionnaire requesting information regarding

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maternal characteristics and ultrasound measurements. The questionnaire may be presented to the user in paper format and input to fetal birth weight/macrosomic risk estimation software **110** by a patient, a relative, a friend, or a technician or other user, such as a physician or other type of obstetrical practitioner. Alternatively, fetal birth weight/macrosomia risk estimation software may be present the user with the questionnaire via display **116** or via computer network **114**. The following is an example questionnaire that may be presented to a user to collect information for estimating fetal weight at birth and/or risk of macrosomia.

10

Example Questionnaire

- 1) How tall is the patient (enter height in either feet and inches or centimeters)?
- 2) What best characterizes the patient's racial/ethnic group?
 - a) North American Caucasian
 - 15 b) South American Caucasian
 - c) Western European Caucasian
 - d) Eastern European Caucasian
 - e) Australian/ New Zealand Caucasian
 - 20 f) Russian/ Asian Caucasian
 - g) East Indian
 - h) Pakistani
 - i) North African
 - j) African American (Black)
 - k) Japanese
 - 25 l) Chinese
 - m) Vietnamese
 - n) Laotian
 - o) Cambodian
 - p) Taiwanese
 - 30 q) Korean
 - r) Other Oriental
 - s) Filipino
 - t) Pacific Islander
 - u) American Indian
 - 35 v) Other (specify)

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- 3) How much did the patient weigh immediately before she became pregnant (enter weight in either pounds and ounces or kilograms)?
- 4) How much did the patient weigh at the time of her 26-week (six-month) check up (enter weight in either pounds and ounces or kilograms)?
- 5 5) When was the date of the patient's 26-week check-up when her weight was obtained (enter as MM/DD/YYYY)?
- 6) What was the patient's weight at the time of her most recent check-up (enter weight in either pounds and ounces or kilograms)?
- 10 7) What was the date of the patient's most recent check-up when her weight was measured (enter as MM/DD/YYYY)?
- 8) What was the first day of the patient's last normal menstrual period (enter as MM/DD/YYYY)?
- 9) Did the patient's menstrual periods occur regularly each month before her last menstrual period (enter Yes/ No)?
- 15 10) What was the interval at which the patient's menstrual periods occurred prior to becoming pregnant (enter either interval between the beginning of one menstrual period and the next in days, or "range from-to" if a known range in menstrual intervals was present, or "variable" if no consistent pattern was present)?
- 20 11) Was the patient using hormonal contraception when she became pregnant (enter Yes/ No)?
If the answer is Yes, was the contraceptive method either:
- 25 a) Oral Contraceptives (birth control pills)
b) Depo-Provera (a progestin administered by injection, generally every 3 months)
c) Norplant (an implantable progestational contraceptive)
d) Lunelle (an injectable monthly combination estrogen/progestin contraceptive)
30 e) Nuva-Ring (an estrogen/progestin-containing vaginal ring worn for three weeks out of four)
f) Mirena IUD (progestin-containing intrauterine device)
g) Ortho-Evra estrogen/progestin contraceptive Patch
h) Other hormonal contraceptive (specify)
- 35 12) What was the date when the patient's first obstetrical ultrasound examination was performed (enter date as MM/DD/YYYY)?
- 13) How many weeks pregnant did the patient's first ultrasound examination say that she was on the date it was performed (enter number of weeks as either a decimal number, e.g., 8.4 weeks, or as number of weeks plus number of days, e.g., 8 weeks 3 days)?
- 40 14) Did the patient have either an amniocentesis or chorionic villus sampling performed during this pregnancy (enter Yes/ No)?
a) If she had either an amniocentesis or chorionic villus sampling performed, were the results normal (enter either Normal/ Abnormal)?
45 b) If the results were Abnormal, what was the type of abnormality (specify)?

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- 15) Does the patient have a personal history of diabetes mellitus (a high blood sugar problem) (enter Yes/ No)?
- 16) At some time during the patient's pregnancy, she should have had a 1-hour 50-gram oral glucose screening test to rule out diabetes mellitus:
- 5 a) What was the result of the 1-hour 50-gram glucose screening test result (enter as either [gm/dL] or [mg%])?
- b) What was the date when the 1-hour 50-gram glucose screening test was performed (enter as MM/DD/YYYY)?
- 17) Did the patient have a formal 3-hour 100-gm glucose tolerance test performed during this pregnancy (enter Yes/No)?
- 10 a) If she did have a 3-hour 100-gm glucose tolerance test performed, what was the date (enter as MM/DD/YYYY)?
- b) If she did have a 3-hour 100-gm glucose tolerance test performed, what were the results (enter "fasting blood sugar result", "1-hour blood sugar result", "2-hour blood sugar result", and "3-hour blood sugar result")?
- 15 18) Do you know the sex of the patient's fetus (enter male, female, or unknown)?
- 19) How many prior babies has the patient delivered (enter number of prior babies)?
- 20 20) What was the date of the patient's most recent prior delivery (enter as MM/DD/YYYY)?
- 21) How many weeks pregnant was the patient when she delivered her last baby (enter the number of weeks and days that she was pregnant at the time of her last delivery)?
- 25 22) What was the weight of the patient's last baby at the time of delivery (enter weight in either pounds and ounces or kilograms)?
- 23) What was the patient's last baby's sex (enter male, female, or unknown)?
- 24) Were there any congenital anomalies in the patient's last baby (enter Yes/No)?
- 30 a) If the answer is Yes, specify the type of abnormality (enter either None or specify type).
- 25) What was the patient's most recent blood hemoglobin concentration (enter hemoglobin level in grams per deciliter, or [gm/dl])?
- 26) When was the patient's most recent hemoglobin level obtained (enter as MM/DD/YYYY)?
- 35 27) When was the patient's most recent obstetrical ultrasound examination (enter as MM/DD/YYYY)?
- 28) What was the abdominal circumference measurement (AC measurement) of the fetus's abdomen on the date of the most recent ultrasound examination (enter numerical result in mm)?
- 40 29) What was the head circumference measurement (HC measurement) of the fetus's head on the date of the most recent ultrasound examination (enter numerical result in mm)?
- 30) What was the biparietal diameter measurement (BPD measurement) of the fetus's head on the date of the most recent ultrasound examination (enter numerical result in mm)?
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- 31)What was the femur length measurement (FL measurement) of the fetus's thigh on the date of the most recent ultrasound examination (enter numerical result in mm)?
- 5 32)Were there any abnormalities discovered at the time of any of the ultrasound studies that were performed for this patient (enter Yes/ No)?
a) If there were abnormalities discovered, what were they (enter either None or specify type of abnormality)?
- 33)Does the patient have chronic hypertension (high blood pressure) (enter Yes/ No)?
- 10 34)Does the patient have either pregnancy-induced hypertension or pre-eclampsia (enter Yes/ No)?
- 35)Does the patient have any other major medical illnesses (enter either None or specify type)?
- 15 36)Does the patient use any glucocorticoid medications (examples: Prednisone, Prednisolone, Medroxyprogesterone, Cortisone, Hydrocortisone, Dexamethasone, or Betamethasone) (enter Yes/ No)?
- 37)Does the patient use Terbutaline on a chronic basis (enter Yes/ No)?
- 38)Does the patient take any other medications on a chronic basis (enter Yes/ No)?
- 20 a) If the answer is Yes, what type (specify)?
- 39)Does the patient smoke cigarettes (enter Yes/No)?
a) If Yes, how many cigarettes are smoked per day during pregnancy (enter number)?
- 25 40)Does the patient use illicit drugs (enter Yes/No)?
a) If the answer is Yes, what type (specify)?
- 41)At what altitude does the patient live (enter altitude above mean sea level for the city or town in either feet or meters)?
- 42)How tall is the father of the baby (enter his height in either feet and inches or cm)?
- 30 43)Was there ovum donation associated with the current pregnancy (enter Yes/ No)?
- 44)Was there sperm donation associated with the current pregnancy (enter Yes/ No)?

35 The present invention is not limited to obtaining patient information using the questionnaire above. Questions may be modified, added or deleted without departing from the scope of the invention.

Abbreviations and Equations

Fetal birth weight/macrosomia risk estimation software 110 preferably
40 utilizes a hierarchy of equations in order to estimate fetal weight at birth and/or

risk of macrosomia. The operation of fetal birth weight/macrosomic risk estimation software 110 will be explained with regard to the flow charts illustrated in Figures 3A-4B. The flow charts reference equations by numbers. All of the variables and terms that are incorporated in each of the different equations are unique predictors of fetal weight that are specifically and uniquely operational within the context of each equation. Thus, each variable and term in each of the different equations explains an independent portion of the variance in fetal birth weight that the other variables and terms in each individual equation cannot. As such, and within a hierarchy of predictive accuracy that depends exclusively upon the type and quality of maternal and fetal ultrasonographic information that is available, each equation stands alone in its ability to predict fetal weight at birth. Examples of equations and abbreviations used in the equations and the flow charts illustrated in Figure 3A-4B are as follows:

15 BWT = Patient's predicted birth weight, in grams

Day0 = Due date (expected date of confinement) minus 280 = Date of the first day of the last normal menstrual period = Conception date minus 14 days

20 Target Date = date for which birth weight prediction and/or fetal macrosomia risk prediction is desired

GA = Gestational age (days since Day0) on target date

AC = Fetal abdominal circumference as measured by ultrasonography, in mm

25 HC = Fetal head circumference in as measured by ultrasonography, in mm

BPD = Fetal biparietal diameter in as measured by ultrasonography, in mm

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- FL = Fetal femur length in as measured by ultrasonography, in mm
- DeltaUS= Number of elapsed days between fetal ultrasonographic measurements and target date
- Parity = Number of prior babies delivered
- 5 Height = Patient's height, in cm
- Hgb = Patient's third trimester venous hemoglobin concentration, in grams per deciliter
- Prior = Birth weight of patient's previous term newborn, in grams
- 10 PPW = The patient's weight immediately prior to the current pregnancy, in kg
- Wt_{Last} = The last recorded weight for the patient for which an associated gestational age is known, in kg
- GA_{Last} = The gestational age (days since Day0) on which Wt_{Last} was measured
- 15 Wt_{2ndLast} = The 2nd-last recorded weight of the patient (i.e., the weight immediately preceding Wt_{Last}), in kg
- GA_{2ndLast} = The gestational age (days since Day0) on which Wt_{2ndLast} was measured
- Wt₁₈₂ = Patient's weight 182 days after Day0, in kg
- 20 Rate_{3rd} = Patient's weight gain rate during the 3rd trimester, in kg per day
- Equation 1: $BWT = -4147 + (9.693 \times AC) + (11.92 \times HC) + (21.21 \times \text{DeltaUS}) + (3.429 \times GA \times \text{Rate}_{3rd} \times [\text{Parity} + 1])$
- Equation 2: $BWT = -4280 + (9.633 \times AC) + (12.48 \times HC) + (21.66 \times \text{DeltaUS}) + (0.1822 \times GA \times [\text{Parity} + 1])$
- 25 Equation 3: $BWT = -3468 + (10.95 \times AC) + (28.83 \times BPD) + (19.86 \times \text{DeltaUS}) + (0.00007464 \times GA \times \text{Height} \times \text{Wt}_{182}) + (3.336 \times GA \times \text{Rate}_{3rd} \times [\text{Parity} + 1])$
- Equation 4: $BWT = -3337 + (10.96 \times AC) + (27.61 \times BPD) + (20.16 \times \text{DeltaUS}) + (0.0001027 \times GA \times \text{Height} \times \text{Wt}_{182})$
- 30 Equation 5: $BWT = -3726 + (11.17 \times AC) + (33.18 \times BPD) + (21.14 \times \text{DeltaUS}) + (3.817 \times GA \times \text{Rate}_{3rd} \times [\text{Parity} + 1])$
- Equation 6: $BWT = -3814 + (11.27 \times AC) + (34.17 \times BPD) + (21.59 \times \text{DeltaUS}) + (0.1970 \times GA \times [\text{Parity} + 1])$

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- Equation 7: $BWT = -2495 + (11.87 \times AC) + (18.39 \times FL) + (18.79 \times \Delta US) + (0.00008700 \times GA \times Height \times Wt_{182}) + (3.260 \times GA \times Rate_{3rd} \times [Parity + 1])$
- 5 Equation 8: $BWT = -2388 + (11.87 \times AC) + (17.23 \times FL) + (19.07 \times \Delta US) + (0.0001142 \times GA \times Height \times Wt_{182})$
- Equation 9: $BWT = -2644 + (12.38 \times AC) + (21.58 \times FL) + (20.17 \times \Delta US) + (3.797 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 10: $BWT = -2547 + (12.52 \times AC) + (21.37 \times FL) + (20.88 \times \Delta US)$
- 10 Equation 11: $BWT = -1627 + (13.18 \times AC) + (16.23 \times \Delta US) + (0.00009964 \times GA \times Height \times Wt_{182}) + (3.173 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 12: $BWT = -1576 + (13.10 \times AC) + (16.66 \times \Delta US) + (0.0001254 \times GA \times Height \times Wt_{182})$
- 15 Equation 13: $BWT = -2469 + (13.09 \times AC) + (16.17 \times \Delta US) + (0.02625 \times GA \times Height) + (3.812 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 14: $BWT = -2501 + (13.28 \times AC) + (16.51 \times \Delta US) + (0.02647 \times GA \times Height) + (0.1877 \times GA \times [Parity + 1])$
- 20 Equation 15: $BWT = -4260 + (15.57 \times HC) + (27.33 \times FL) + (17.55 \times \Delta US) + (0.00008659 \times GA \times Height \times Wt_{182}) + (2.902 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 16: $BWT = -4225 + (15.80 \times HC) + (26.12 \times FL) + (17.95 \times \Delta US) + (0.0001112 \times GA \times Height \times Wt_{182})$
- 25 Equation 17: $BWT = -4639 + (17.37 \times HC) + (27.90 \times FL) + (18.97 \times \Delta US) + (3.326 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 18: $BWT = -4666 + (17.97 \times HC) + (27.06 \times FL) + (19.79 \times \Delta US)$
- 30 Equation 19: $BWT = -3840 + (12.69 \times HC) + (27.33 \times BPD) + (15.11 \times \Delta US) + (0.00009689 \times GA \times Height \times Wt_{182}) + (2.898 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 20: $BWT = -3810 + (13.25 \times HC) + (25.21 \times BPD) + (15.58 \times \Delta US) + (0.0001210 \times GA \times Height \times Wt_{182})$
- 35 Equation 21: $BWT = -4222 + (14.33 \times HC) + (28.71 \times BPD) + (16.56 \times \Delta US) + (3.392 \times GA \times Rate_{3rd} \times [Parity + 1])$

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- Equation 22: $BWT = -4234 + (15.44 \times HC) + (26.06 \times BPD) + (17.40 \times \Delta US)$
- 5 Equation 23: $BWT = -3383 + (18.85 \times HC) + (13.95 \times \Delta US) + (0.00009838 \times GA \times Height \times Wt_{182}) + (2.757 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 24: $BWT = -3388 + (18.93 \times HC) + (14.49 \times \Delta US) + (0.0001213 \times GA \times Height \times Wt_{182})$
- Equation 25: $BWT = -3764 + (20.88 \times HC) + (15.40 \times \Delta US) + (3.239 \times GA \times Rate_{3rd} \times [Parity + 1])$
- 10 Equation 26: $BWT = -3816 + (21.37 \times HC) + (16.30 \times \Delta US)$
- Equation 27: $BWT = -3492 + (45.16 \times BPD) + (30.75 \times FL) + (16.35 \times \Delta US) + (0.00009699 \times GA \times Height \times Wt_{182}) + (3.453 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 28: $BWT = -3326 + (44.25 \times BPD) + (29.95 \times FL) + (16.53 \times \Delta US) + (0.0001266 \times GA \times Height \times Wt_{182})$
- 15 Equation 29: $BWT = -4277 + (45.49 \times BPD) + (29.51 \times FL) + (16.18 \times \Delta US) + (0.02549 \times GA \times Height) + (4.073 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 30: $BWT = -4352 + (47.04 \times BPD) + (28.85 \times FL) + (16.46 \times \Delta US) + (0.02596 \times GA \times Height) + (0.2127 \times GA \times [Parity + 1])$
- 20 Equation 31: $BWT = -1028 + (52.61 \times FL) + (11.38 \times \Delta US) + (0.0001424 \times GA \times Height \times Wt_{182}) + (3.221 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 32: $BWT = -907.5 + (51.28 \times FL) + (11.60 \times \Delta US) + (0.0001693 \times GA \times Height \times Wt_{182})$
- 25 Equation 33: $BWT = -2183 + (50.45 \times FL) + (10.98 \times \Delta US) + (0.03900 \times GA \times Height) + (4.145 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 34: $BWT = -1993 + (50.91 \times FL) + (11.66 \times \Delta US) + (0.03719 \times GA \times Height)$
- 30 Equation 35: $BWT = -2330 + (56.44 \times BPD) + (11.67 \times \Delta US) + (0.0001188 \times GA \times Height \times Wt_{182}) + (3.372 \times GA \times Rate_{3rd} \times [Parity + 1])$
- Equation 36: $BWT = -3444 + (55.51 \times BPD) + (11.58 \times \Delta US) + (0.03485 \times GA \times Height) + (4.142 \times GA \times Rate_{3rd} \times [Parity + 1])$
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- Equation 37: $BWT = -2189 + (55.16 \times BPD) + (11.93 \times \Delta US) + (0.0001475 \times GA \times Height \times Wt_{182})$
- Equation 38: $BWT = -3558 + (56.89 \times BPD) + (11.93 \times \Delta US) + (0.03529 \times GA \times Height) + (0.2334 \times GA \times [Parity + 1])$
- 5 Equation 39: $BWT = -3651 + (70.47 \times BPD) + (14.60 \times \Delta US) + (0.1853 \times Prior)$
- Equation 40: $BWT = -1212 + GA \times [13.69 + (0.2419 \times Gender\#) + (0.0002004 \times Height \times Wt_{182}) + (11.59 \times Rate_{3rd})] - (40.75 \times Hgb) + (0.1598 \times Prior)$
- 10 Equation 41: $BWT = -1316 + GA \times [14.50 + (0.2574 \times Gender\#) + (0.0002175 \times Height \times Wt_{182})] - (39.33 \times Hgb) + (0.1697 \times Prior)$
- Equation 42: $BWT = -2214 + GA \times [17.49 + (0.2607 \times Gender\#) + (12.03 \times Rate_{3rd})] + (0.1987 \times Prior)$
- 15 Equation 43: $BWT = -2387 + GA \times [18.72 + (0.2767 \times Gender\#)] + (0.2179 \times Prior)$
- Equation 44: $BWT = -1727 + GA \times [17.44 + (0.2346 \times Gender\#) + (0.0002106 \times Height \times Wt_{182}) + (3.350 \times Rate_{3rd} \times \{Parity + 1\})] - (39.05 \times Hgb)$
- 20 Equation 45: $BWT = -1547 + GA \times [17.13 + (0.2322 \times Gender\#) + (0.0002270 \times Height \times Wt_{182})] - (40.93 \times Hgb)$
- Equation 46: $BWT = -1689 + GA \times [13.19 + (0.2556 \times Gender\#) + (0.03884 \times Height) + (4.072 \times Rate_{3rd} \times \{Parity + 1\})] - (33.88 \times Hgb)$
- 25 Equation 47: $BWT = -1611 + GA \times [12.68 + (0.2593 \times Gender\#) + (0.04144 \times Height) + (0.1755 \times \{Parity + 1\})] - (33.40 \times Hgb)$
- Equation 48: $BWT = -1643 + GA \times [15.92 + (0.2441 \times Gender\#) + (0.0001998 \times Height \times Wt_{182}) + (1.552 \times Rate_{3rd} \times \{Parity + 1\})]$
- 30 Equation 49: $BWT = -1677 + GA \times [15.87 + (0.2596 \times Gender\#) + (0.0002059 \times Height \times Wt_{182}) + (0.1779 \times \{Parity + 1\})]$
- Equation 50: $BWT = -1553 + GA \times [11.55 + (0.2614 \times Gender\#) + (0.03916 \times Height) + (1.882 \times Rate_{3rd} \times \{Parity + 1\})]$
- 35 Equation 51: $BWT = -1576 + GA \times [11.92 + (0.2750 \times Gender\#) + (0.03629 \times Height) + (0.2123 \times \{Parity + 1\})]$

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$$\text{Equation 52: BWT} = \text{GA} \times [10.16 + (0.3596 \times \text{Gender\#}) + (0.0001201 \times \text{Height} \times \text{Wt}_{182}) + (4.297 \times \text{Rate}_{3\text{rd}})]$$

$$\text{Equation 53: BWT} = \text{GA} \times [10.43 + (0.3783 \times \text{Gender\#}) + (0.0001327 \times \text{Height} \times \text{Wt}_{182})]$$

$$5 \quad \text{Equation 54: BWT} = \text{GA} \times [(0.4209 \times \text{Gender\#}) + (0.07123 \times \text{Height}) + (3.971 \times \text{Rate}_{3\text{rd}})]$$

$$\text{Equation 55: BWT} = \text{GA} \times [(0.3920 \times \text{Gender\#}) + (0.07303 \times \text{Height})]$$

$$\text{Equation 56: BWT} = \text{GA} \times [8.823 + (0.0003013 \times \text{Height} \times \text{Wt}_{182})]$$

$$10 \quad \text{Equation 57: BWT} = -1243 + \text{GA} \times [(0.2741 \times \text{Gender\#}) + (0.1042 \times \text{Height})]$$

$$\text{Equation 58: BWT} = -1770 + \text{GA} \times [16.25 + (0.0001676 \times \text{Height} \times \text{Wt}_{182}) + (4.826 \times \text{Rate}_{3\text{rd}} \times \{\text{Parity} + 1\})]$$

$$\text{Equation 59: BWT} = -1469 + \text{GA} \times [15.44 + (0.0002050 \times \text{Height} \times \text{Wt}_{182})]$$

$$15 \quad \text{Equation 60: BWT} = \text{GA} \times [(0.07227 \times \text{Height}) + (5.410 \times \text{Rate}_{3\text{rd}} \times \{\text{Parity} + 1\})]$$

$$\text{Equation 61: BWT} = -1874 + (\text{GA} \times 18.77)$$

In the equations listed above, numeric constants are included to facilitate calculation of fetal weight at birth and risk of macrosomia. These constants were obtained based on experimental data. However, the present invention is not limited to using these exact constants. These constants are merely illustrated to illustrate the best mode known for practicing the invention at the time of filing. One or more of the numeric constants in each equation may be changed without departing from the scope of the invention.

Fetal Birth Weight/Macrosomic Risk Estimation Program Flow

Figures 3A-4B illustrate exemplary steps that may be performed by fetal birth weight/macrosomia risk estimation software 110 in estimating fetal birth weight and/or risk of macrosomia. Referring to Figure 3A, in step ST1, the

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program determines whether the expected due date is known. The expected due date may be determined using any suitable method. For example, one method for calculating the expected due date is adding 280 days to the first day of the patient's last normal menstrual period. Another method is adding thirty-
5 eight weeks to the fertilization date. Yet another method for estimating the expected due date is to use ultrasound measurements to determine the approximate age of the fetus and to predict the expected due date based on the age. If the expected due date is not known, control proceeds to step **ST2** where the birth weight cannot be predicted. After this step, processing for
10 estimating fetal birth weight ends.

If the expected due date is known, control proceeds to step **ST3** where the program determines whether the patient's (i.e., the mother's) height is known. If the patient's height is not known, control proceeds to step **ST2** where the program determines that birth weight cannot be predicted. If the patient's
15 height is known, control proceeds to step **ST4** where the program determines whether the patient's parity is known. As indicated above, the term parity refers to the number of prior children to which the patient has given birth. If the patient's parity is not known, control proceeds to step **ST2**, where the program determines that birth weight cannot be predicted.

20 If, on the other hand, the program determines that the patient's parity is known, control proceeds to step **ST5** where the program calculates the value for a variable referred to herein as Day0 (defined above). In step **ST6**, the program calculates whether the target date minus Day0 is between 259 and

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300 days inclusive. As used herein, the term "target date" refers to the date for which birth weight or risk of macrosomia will be predicted. If the program determines that the target date minus Day0 is not between 259 and 300 days inclusive, control proceeds to step **ST2** where the program determines that
5 birth weight cannot be predicted.

If the program determines that the target date minus Day0 is between 259 and 300 days inclusive, control proceeds to step **ST7** where the program determines whether the patient has diabetes. If the patient has diabetes, control proceeds to step **ST2** where the program determines that birth weight
10 cannot be predicted. If the program determines that the patient does not have diabetes, control proceeds to step **ST8** where the program determines whether the patient has a singleton pregnancy. If the program determines that the patient does not have a singleton pregnancy, control proceeds to step **ST2** where the program determines that birth weight cannot be predicted.

15 If the program determines that the patient does have a singleton pregnancy, control proceeds to step **ST9** where the program stores a value indicative of fetal gender. In the illustrated example, a negative 1 is stored for female fetuses, a positive 1 is stored for male fetuses, and a 0 is stored if fetal gender is unknown.

20 In step **ST10**, the program determines whether the last recorded weight of the patient and the gestational age at the time of the last recorded weight are both known. As indicated above in the definitions section, the gestational age is the days since Day0 on which the patient's weight was last measured. If the

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last recorded weight of the patient and the gestational age at the time of the last recorded weight are not both known, control proceeds to step **ST13**, where the program determines that the patient's weight at 182 days is unknown, and to step **ST15**, where the program determines that the patient's third trimester weight gain rate is unknown. Control then proceeds to the flow chart illustrated in Figure 3B through connector A in Figure 3A.

If in step **ST10**, the program determines that the last recorded weight of the patient and the gestational age at the time of the last recorded weight are both known, control proceeds to step **ST11** where it is determined whether the gestational age of the fetus on the day on which the patient's weight was last measured is greater than 188 days. If the gestational age is not greater than 188 days control proceeds to step **ST12** where the program determines whether the gestational age on the day on which the patient's weight was last measured is greater than 173 days. If the age is not greater than 173 days control proceeds to step **ST13** where it is determined that the patient's weight 182 days after Day0 is not known.

If in step **ST12**, the program determines that the age was between 173 and 188 days at the last weight measurement, control proceeds to step **ST14** where the program sets the weight at 182 days to the patient's last weight measurement. Control then proceeds to step **ST15** where the program determines that the rate of weight gain during the third trimester is unknown. If in step **ST11**, the program determines that the gestational age on the day of the patient's last weight measurement is greater than 188 days, control

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proceeds to step **ST16** where the program determines whether the patient's second-to-last weight measurement and the corresponding gestational age are both known. If both are not known, control proceeds to step **ST17** where the program determines whether the patient's pre-pregnancy weight is known. If the patient's pre-pregnancy weight is not known, control proceeds to steps **ST13** and **ST15** where the program determines that the patient's weight at 182 days is not known and that the patient's rate of weight gain during the third trimester is not known. If rate of weight gain during the third trimester and weight at 182 days are both unknown, control proceeds to the flow chart illustrated in Figure 3B through connector A in Figure 3A.

Returning to step **ST16**, if the second-to-last weight measurement and the corresponding gestational age are both known, control proceeds to step **ST18**, where the program calculates the rate of weight gain during the third trimester. Control then proceeds to step **ST19** where the program uses the rate of third trimester weight gain calculated in step **ST18** to calculate the patient's weight corresponding to a gestational age of 182 days (hereinafter, "patient's weight at 182 days"). Similarly, in step **ST17**, if the pre-pregnancy weight is known, in step **ST20**, the rate of weight gain during the third trimester is calculated using the pre-pregnancy weight and control proceeds to step **ST19** where the patient's weight at 182 days is calculated.

Once the program either calculates the weight at 182 days and the third trimester weight gain rate or determines that the weight or the third trimester weight gain rate, or both, are unknown, control proceeds to the flow chart

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illustrated in Figure 3B through connector A. Referring to Figure 3B, in step **ST21**, the program determines whether any or all of the following four ultrasound measurements were taken within seventy days of the target date: fetal biparietal diameter (BPD), fetal head circumference (HC), fetal abdominal circumference (AC), and fetal femur length (FL). If any or all of these measurements were taken within seventy days of the target date, control proceeds to the flow chart illustrated in Figure 3C through connector B in Figure 3B. If any or all of the measurements in step **ST21** were not taken within seventy days of the target date, control proceeds to step **ST22** where the program determines whether the patient is Caucasian. If the patient is Caucasian, control proceeds to the flow chart illustrated in Figure 3F through connector C in Figure 3B. If the program determines that the patient is not Caucasian, control proceeds to the flow chart illustrated in Figure 3G through connector D illustrated in Figure 3B.

Figure 3C illustrates exemplary steps that may be performed by fetal birth weight calculation/macrosomia risk estimation software **110** illustrated in Figure 1 if certain ultrasound measurements were taken within seventy days of the target date. Referring to Figure 3C, in step **ST23**, the program computes a quantity DeltaUS, which indicates the number of days that elapse between the fetal ultrasonographic measurements and the target date. In step **ST24**, the program determines whether fetal abdominal circumference (AC) was measured at the last ultrasound. If fetal abdominal circumference (AC) was not

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measured at the last ultrasound, control proceeds to the flow chart illustrated in Figure 3D through connector E in Figure 3C.

In step **ST24**, if the program determines that fetal abdominal circumference (AC) was measured at the last ultrasound, control proceeds to step **ST25** where the program determines whether the fetal head circumference (HC) was measured at the last ultrasound. If the fetal head circumference (HC) was measured at the last ultrasound, control proceeds to step **ST26** where the program determines whether the rate of weight gain during the third trimester is known. If the rate of weight gain during the third trimester is known, the program uses Equation 1 listed above to predict birth weight. In step **ST26**, if the program determines that the rate of weight gain during the third trimester is not known, program uses Equation 2 listed above to predict birth weight (step **ST28**).

Returning to step **ST25**, if the fetal head circumference (HC) was not measured at the last ultrasound, control proceeds to step **ST29** where the program determines whether the fetal biparietal diameter (BPD) was measured at the last ultrasound. If biparietal diameter was measured at the last ultrasound, control proceeds to step **ST30** where the program determines whether the patient's weight at 182 days and the rate of weight gain during the third trimester are known. If both are known, in step **ST31**, the program uses Equation 3 to predict birth weight. If only the patient's weight at 182 days is known but not the rate of maternal weight gain during the third trimester, the program uses Equation 4 to predict birth weight (step **ST32**). If only the rate of

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weight gain during the third trimester is known but not the patient's weight at 182 days, the program uses Equation 5 to predict birth weight (step **ST33**). If neither parameter is known, control proceeds to step **ST34** where the program uses Equation 6 to predict birth weight.

Returning to step **ST29**, if the fetal biparietal diameter (BPD) was not measured at the last ultrasound, control proceeds to step **ST35** where the program determines whether the fetal femur length (FL) was measured at the last ultrasound. If the fetal femur length (FL) was measured at the last ultrasound, control proceeds to step **ST36** where the program determines whether rate of weight gain during the third trimester and the patient's weight at 182 days are known. If both parameters are known, in step **ST37**, the program uses Equation 7 to predict birth weight. If only the patient's weight at 182 days is known, program uses Equation 8 to predict birth weight (step **ST38**). If only the rate of weight gain during the third trimester is known, the program uses Equation 9 to predict birth weight (step **ST39**). Finally, if neither the patient's weight at 182 days nor rate of weight gain during the third trimester is known, the program uses Equation 10 to predict birth weight (step **ST40**).

Returning again to step **ST35**, if the fetal femur length (FL) was not measured at the last ultrasound, control proceeds to step **ST41** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If both parameters are known, in step **ST42**, the program uses Equation 11 to predict birth weight. If only the patient's weight at 182 days is known, the program uses Equation 12 to predict

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birth weight (step **ST43**). If only the rate of weight gain during the third trimester is known, the program uses Equation 13 to predict birth weight (step **ST44**). Finally, if neither parameter is known, the program uses Equation 14 to predict birth weight (step **ST45**).

Figure 3D illustrates exemplary steps performed by fetal birth weight/macrosomia risk estimation software **110** in estimating fetal birth weight if the fetal abdominal circumference (AC) was not measured at the last ultrasound. Entry is via connector E from the preceding flow sheet 3C at **ST24**.

Referring to Figure 3D, in step **ST46**, the program determines whether the fetal head circumference (HC) was measured at the last ultrasound. If the fetal head circumference (HC) was not measured at the last ultrasound, control proceeds to the flow chart illustrated in Figure 3E through connector F. If the fetal head circumference (HC) was measured at the last ultrasound, control proceeds to step **ST47** where the program determines whether the fetal femur length (FL) was measured at the last ultrasound. If the fetal femur length (FL) was measured at the last ultrasound, control proceeds to step **ST48** where the program determines whether the patient's weight at a gestational age of 182 days and rate of weight gain during the third trimester are known. If both are known, the program uses Equation 15 to predict birth weight (step **ST49**). If only the patient's weight at 182 days is known, the program uses Equation 16 to predict birth weight (step **ST50**). If only the rate of weight gain during the third trimester is known, the program uses Equation 17 to predict birth weight

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(step **ST51**). Finally, if neither of the parameters is known, the program uses Equation 18 to predict birth weight (step **ST52**).

Returning to step **ST47**, if the fetal femur length (FL) was not measured at the last ultrasound, control proceeds to step **ST53** where the program determines whether the fetal biparietal diameter (BPD) was measured at the last ultrasound. If the fetal biparietal diameter (BPD) was measured at the last ultrasound, the program proceeds to step **ST54** and determines whether the patient's weight at 182 days and rate of weight gain during third trimester are known. If both are known, the program uses Equation 19 to predict birth weight (step **ST55**). If only the patient's weight at 182 days is known, the program uses Equation 20 to predict birth weight (step **ST56**). If only the rate of weight gain during the third trimester is known, the program uses Equation 21 to predict birth weight (step **ST57**). If neither parameter is known, the program uses Equation 22 to predict birth weight (step **ST58**).

Returning to step **ST53**, if the fetal biparietal diameter (BPD) was not measured at the last ultrasound, control proceeds to step **ST59** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If both parameters are known, the program uses Equation 23 to predict birth weight (**ST60**). If only the patient's weight at 182 days is known, the program uses Equation 24 to predict birth weight (step **ST61**). If only the rate of weight gain during the third trimester is known, the program uses Equation 25 to predict birth weight (**ST62**). Finally, if neither rate of weight gain during the third trimester nor the

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patient's weight at 182 days is known, the program uses Equation 26 to predict birth weight (**ST63**).

Figure 3E illustrates exemplary steps that may be performed by fetal birth weight/macrosomia risk estimation software **110** in estimating birth weight if the fetal head circumference (HC) was not measured at the last ultrasound. Entry is via connector F from the preceding flow chart 3D at **ST46**. Referring to Figure 3E, in step **ST64**, the program determines whether the fetal femur length (FL) was measured at the last ultrasound. If femur length was measured at the ultrasound, control proceeds to step **ST65** where the program determines whether the fetal biparietal diameter (BPD) was measured at the last ultrasound. If the fetal biparietal diameter (BPD) was measured at the last ultrasound, control proceeds to step **ST66** where the program determines whether the patient's weight at 182 days and rate of weight gained during the third trimester are known. If both parameters are known, the program uses Equation 27 to predict birth weight (step **ST67**). If only the patient's weight at 182 days is known, the program uses Equation 28 to predict birth weight (step **ST68**). If only the rate of weight gain during the third trimester is known, the program uses Equation 29 to predict birth weight (step **ST69**). If neither parameter is known, the program uses Equation 30 to predict birth weight (step **ST70**).

Returning to step **ST65**, if the fetal biparietal diameter (BPD) was measured at the last ultrasound, control proceeds to step **ST71** where the program determines whether the patient's weight at 182 days and rate of

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weight gain during third trimester are known. If both are known, the program uses Equation 31 to predict birth weight (step **ST72**). If only the patient's weight at 182 days is known, the program uses Equation 32 to predict birth weight (step **ST73**). If only the rate of weight gain during the third trimester is known, the program uses Equation 33 to predict birth weight (step **ST74**). If neither parameter is known, the program uses Equation 34 to predict birth weight (step **ST75**).

Returning to step **ST64**, if the fetal femur length (FL) was measured at the last ultrasound, control proceeds to step **ST76** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If both parameters are known, the program uses Equation 35 to predict birth weight (step **ST77**). If only the patient's weight at 182 days is known, the program uses Equation 36 to predict birth weight (step **ST78**). If only the rate of weight gain during the third trimester is known, the program uses Equation 37 to predict birth weight (step **ST79**).

If neither parameter is known, control proceeds to step **ST80** where the program determines whether the patient has delivered a term pregnancy previously. If the patient has not delivered a term pregnancy previously, the program uses Equation 38 to predict birth weight (step **ST81**). If the patient has delivered a term pregnancy previously, in step **ST82**, the program determines whether the previous birth weight is known. If the previous birth weight is not known, the program uses Equation 38 to predict birth weight (step

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ST81). If the previous birth weight is known, the program uses Equation 39 to predict birth weight (step **ST83**).

Figure 3F illustrates exemplary steps that may be performed by fetal birth weight/macrosomia risk estimation software **110** for Caucasian patients. Entry is via connector C from the previous flow sheet 3B in **ST22**. Referring to Figure 3F, in step **ST84** the program determines whether the patient has delivered a term pregnancy previously. If the program determines that the patient has delivered a term pregnancy previously, control proceeds to step **ST85** where the program determines whether the previous birth weight is known. If the previous birth weight is known, control proceeds to step **ST86** where the program determines whether the patient's third trimester venous hemoglobin concentration is known. If the patient's third trimester venous hemoglobin concentration is known, control proceeds to step **ST87** where the program determines whether the patient's weight at 182 days is known. If the program determines that the patient's weight at 182 days is known, control proceeds to step **ST88** where the program determines whether the patient's rate of weight gain during the third trimester is known. If the rate of weight gain during the third trimester is known, the program uses Equation 40 to predict birth weight (step **ST89**). If, at step **ST88**, the rate of weight gain during the third trimester is not known, the program uses Equation 41 to predict birth weight (step **ST90**).

In steps **ST86** or **ST87**, if the hemoglobin measurement or weight at 182 days is not known, control proceeds to step **ST91** where the program

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determines whether the patient's rate of weight gain during the third trimester is known. If the patient's rate of weight gain during the third trimester is known, the program uses Equation 42 to predict birth weight (step **ST92**). If the patient's rate of weight gain during the third trimester is not known, the program uses Equation 43 to predict birth weight (step **ST93**).

In steps **ST84** and step **ST85**, if the program determines that the patient did not deliver a term pregnancy previously or that the previous birth weight was not known, control proceeds to step **ST94** where the program determines whether the patient's venous hemoglobin concentration during the third trimester is known. If the patient's hemoglobin concentration is known, control proceeds to step **ST95** where the program determines whether the patient's weight at 182 days and the rate of weight gain during the third trimester are known. If both parameters are known, program uses Equation 44 to predict birth weight (step **ST96**). If only weight at 182 days is known, the program uses Equation 45 to predict birth weight (step **ST97**). If only the rate of weight gain during the third trimester is known, the program uses Equation 46 to predict birth weight (step **ST98**). If neither parameter is known, the program uses Equation 47 to predict birth weight (step **ST99**).

Returning to step **ST94**, if the program determines that the venous hemoglobin concentration during the third trimester is not known, control proceeds to step **ST100** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If both parameters are known, the program uses Equation 48 to predict birth

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weight (step **ST101**). If only the patient's weight at 182 days is known, the program uses Equation 49 to predict birth weight (step **ST102**). If only the rate of weight gain during the third trimester is known, the program uses Equation 50 to predict birth weight (step **ST103**). If neither parameter is known, the program uses Equation 51 to predict birth weight (step **ST104**).

Figure 3G is a flow chart illustrating exemplary steps performed by fetal birth weight/macrosomia risk estimation software **110** in estimating fetal birth weight for non-Caucasian patients. Entry is via connector D from previous flow chart 3B at **ST22**. Referring to Figure 3G, in step (**ST105**), the program determines whether the patient is African-American. If the program determines that the patient is African-American, control proceeds to step **ST106** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If both parameters are known, the program uses Equation 52 to predict birth weight (step **ST107**). If only the patient's weight at 182 days is known, the program uses Equation 53 to predict birth weight (step **ST108**). If only the rate of weight gain during the third trimester is known, the program uses Equation 54 to predict birth weight (step **ST109**). If neither parameter is known, the program uses Equation 55 to predict birth weight (**ST110**).

If the program determines in step **ST105** that the patient is not African-American, control proceeds to step **ST111** where the program determines whether the patient is Filipino. If the program determines that the patient is Filipino, control proceeds to step **ST112** where the program determines

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whether the patient's weight at 182 days is known. If the patient's weight at 182 days is known, the program uses Equation 56 to predict birth weight (step **ST113**). If the patient's weight at 182 days is not known, the program uses Equation 57 to predict birth weight (step **ST114**).

In step **ST111**, if the program determines that the patient is not Filipino, control proceeds to step **ST115** where the program determines whether the patient is Oriental. If the patient is Oriental, control proceeds to step **ST116** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If the program determines that both parameters are known, the program uses Equation 58 to predict birth weight (step **ST117**). If the program determines that only the patient's weight at 182 days is known, the program uses Equation 59 to predict birth weight (step **ST118**). If the program determines that only rate of weight gain during the third trimester is known, the program uses Equation 60 to predict birth weight (step **ST119**). If the program determines that neither parameter is known, the program uses Equation 61 to predict birth weight (step **ST120**). Finally, in step **ST115**, if the program determines that the patient is not Oriental, the program may output a message indicating that birth weight cannot be predicted.

Thus, as illustrated in Figures 3A through 3G, fetal birth weight/macrosomia risk estimation software **110** estimates birth weight based on known information and uses the known information to select an optimal and uniquely developed equation in a predetermined hierarchy of equations that will

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allow the output of the most reliable fetal birth weight estimate that is possible given the type of information that is known and available.

In addition to calculating and outputting the predicted birth weight, fetal birth weight/macrosomia risk estimation software **110** may also output confidence intervals associated with each birth weight prediction. These confidence intervals have been determined empirically for each equation. Table 1 shown below illustrates the currently available and exemplary 80% confidence intervals for the equations listed above for estimating fetal birth weight. Using Table 1, 10 percent of actual birth weights can be expected to be below the individually predicted birth weight for each fetus minus the numerical cell entry for each equation, and 10% can be expected to be above the individually predicted birth weight for each fetus plus the numerical cell entry for each equation. Thus, by adding the numerical cell entry for each equation to the individually predicted birth weight for each fetus, the actual birth weight of the fetus on the specified target date will fall at or below the summation value in 90 percent of cases.

Equation	Mean 80% Confidence Interval (in grams)
Equation 1	427
Equation 2	441
Equation 3	422
Equation 4	438
Equation 5	431
Equation 6	447
Equation 7	435
Equation 8	449
Equation 9	448
Equation 10	468
Equation 11	440

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Equation	Mean 80% Confidence Interval (in grams)
Equation 12	454
Equation 13	442
Equation 14	458
Equation 15	471
Equation 16	482
Equation 17	479
Equation 18	494
Equation 19	477
Equation 20	488
Equation 21	485
Equation 22	500
Equation 23	483
Equation 24	492
Equation 25	491
Equation 26	505
Equation 27	494
Equation 28	508
Equation 29	496
Equation 30	512
Equation 31	537
Equation 32	547
Equation 33	539
Equation 34	558
Equation 35	509
Equation 36	509
Equation 37	522
Equation 38	524
Equation 39	567
Equation 40	491
Equation 41	507
Equation 42	521
Equation 43	538
Equation 44	484
Equation 45	495
Equation 46	503
Equation 47	516
Equation 48	492
Equation 49	495
Equation 50	508
Equation 51	523
Equation 52	496
Equation 53	506
Equation 54	487
Equation 55	513

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Equation	Mean 80% Confidence Interval (in grams)
Equation 56	539
Equation 57	541
Equation 58	440
Equation 59	451
Equation 60	437
Equation 61	463

Table 1: Confidence Intervals for Individual Fetal Birth Weight Estimation

Equations

In addition to estimating fetal birth weight, fetal birth weight/macrosomia risk estimation software **110** may also calculate risk of macrosomia. Figures 4A and 4B illustrate exemplary steps that may be performed by fetal birth weight/macrosomia risk estimation software **110** in estimating risk of macrosomia. Referring to Figure 4A, in step **ST1**, the program determines whether the expected due date is known. The expected due date may be estimated using any of the methods described above with regards to Figure 3A. If the expected due date is not known, control proceeds to step **ST2** where the program determines that risk of macrosomia cannot be predicted. After this step, processing for estimating risk of macrosomia ends.

If the expected due date is known, control proceeds to step **ST3** where the program determines whether the patient's (i.e., the mother's) height is known. If the patient's height is not known, control proceeds to step **ST2** where the program determines that risk of macrosomia cannot be predicted. If the patient's height is known, control proceeds to step **ST4** where the program determines whether the patient's parity is known. As indicated above, the term

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parity refers to the number of prior children to which the patient has given birth.

If the patient's parity is not known, control proceeds to step **ST2**, where the program determines that risk of macrosomia cannot be predicted.

If, on the other hand, the program determines that the patient's parity is
5 known, control proceeds to step **ST5** where the program calculates the value
for a variable referred to herein as Day0 (defined above). In step **ST6**, the
program calculates whether the target date minus Day0 is between 259 and
300 days inclusive. If the program determines that the target date minus Day0
is not between 259 and 300 days inclusive, control proceeds to step **ST2** where
10 the program determines that risk of macrosomia cannot be predicted.

If the program determines that the target date minus Day0 is between
259 and 300 days inclusive, control proceeds to step **ST7** where the program
determines whether the patient has Class A₂ insulin-dependent diabetes or
higher. If the patient has Class A₂ insulin-dependent diabetes or higher, control
15 proceeds to step **ST2** where the program determines that risk of macrosomia
cannot be predicted. If the program determines that the patient does not have
Class A₂ insulin-dependent diabetes or higher, control proceeds to step **ST8**
where the program determines whether the patient has a singleton pregnancy.
If the program determines that the patient does not have a singleton
20 pregnancy, control proceeds to step **ST2** where the program determines that
risk of macrosomia cannot be predicted.

If the program determines that the patient has a singleton pregnancy,
control proceeds to step **ST9** where the program determines whether the

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patient's weight and the gestational age at the time of the last weight measurement are both known. If the last recorded weight of the patient and the gestational age at the time of the last recorded weight are not both known, control proceeds to step **ST12**, where the program determines that the patient's weight at 182 days is unknown, and to step **ST14**, where the program determines that the patient's third trimester weight gain rate is unknown. Control then proceeds to step **ST17**, where the program determines whether fetal ultrasound measurements were taken within 70 days of the target date. If fetal ultrasound measurements were taken within 70 days of the target date, control proceeds to the flow chart illustrated in Figure 4B through connector A in Figure 4A. Otherwise, control proceeds to step **ST2**, where the program determines that risk of macrosomia cannot be predicted

If in step **ST9**, the program determines that the last recorded weight of the patient and the gestational age at the time of the last recorded weight are both known, control proceeds to step **ST10** where it is determined whether the gestational age on which the patient's weight was last measured is greater than 188 days. If the gestational age is not greater than 188 days control proceeds to step **ST11** where the program determines whether the gestational age on which the patient's weight was last measured is greater than 173 days. If the age is not greater than 173 days control proceeds to step **ST12** where it is determined that the patient's weight 182 days after is not known.

If in step **ST11**, the program determines that the gestational age corresponding to the day on which the patient's weight was last measured is

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between 173 and 188 days, control proceeds to step **ST13** where the program sets the patient's weight at 182 days to the patient's weight at the last weight measurement. Control then proceeds to step **ST14** where the program determines that the rate of weight gain during the third trimester is unknown. If in step **ST10**, the program determines that the gestational age at the last ultrasound measurement is greater than 188 days, control proceeds to step **ST15** where the program determines whether the second-to-last weight and second-to-last gestational age are both known. If neither parameter is known, control proceeds to step **ST16** where the program determines whether the patient's pre-pregnancy weight is known. If the patient's pre-pregnancy weight is not known, control proceeds to steps **ST12** and **ST14** where the program determines that the patient's weight at 182 days is not known and that the patient's rate of weight gain during the third trimester is not known. If the rate of weight gain during the third trimester and the patient's weight at 182 days are both unknown, control proceeds to step **ST17** where the program determines whether fetal ultrasound measurements were taken within 70 days of the target date. If fetal ultrasound measurements were taken within 70 days of the target date, control proceeds to the flow chart illustrated in Figure 4B through connector A in Figure 4A. Otherwise, if no fetal ultrasound measurements were taken within 70 days of the target date, control proceeds to step **ST2**, where the program determines that risk of macrosomia cannot be predicted.

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Returning to step **ST15** in Figure 4A, if the patient's weight second-to-last measurement and the corresponding gestational age are both known, control proceeds to step **ST18**, where the program calculates the rate of weight gain during the third trimester. Control then proceeds to step **ST19** where the program uses the rate calculated in step **ST18** to calculate the patient's weight at 182 days. Control then proceeds to step **ST17** where the program determines whether fetal ultrasound measurements were taken within seventy days of the target date. Similarly, in step **ST16**, if the pre-pregnancy weight is known, in step **ST20**, the rate of weight gain during the third trimester is calculated using the pre-pregnancy weight and control proceeds to step **ST19** where the patient's weight at 182 days is calculated. Control then proceeds to step **ST17** where the program determines whether fetal ultrasound measurements were taken within seventy days of the target date.

Once the program either calculates the patient's weight at 182 days or determines that the patient's weight at 182 days is not known, control proceeds to the flow chart illustrated in Figure 4B through connector A. Referring to Figure 4B, in step **ST21**, the program computes a quantity DeltaUS, which indicates the number of days elapsed between the time of ultrasonographic fetal measurements and the target date. In step **ST22**, the program determines whether the fetal abdominal circumference (AC) and head circumference (HC) were measured at the last ultrasound. If neither was measured, in step **ST23**, the program determines that risk of macrosomia cannot be predicted. If both were measured, control proceeds to step **ST24** where the program determines

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whether the rate of weight gain during the third trimester is known. If the rate of weight gain during the third trimester is known, the program uses Equation 1 listed above to predict risk of macrosomia (step **ST25**). More particularly, if Equation 1 indicates that the predicted birth weight is greater than a predetermined value, macrosomia is predicted. In one example, the predetermined value for Equation 1 may be about 3850 grams. However, the present invention is not limited to using 3850 grams as the value for indicating macrosomia. Any suitable value for predicting risk of macrosomia is intended to be within the scope of the invention. In addition, as indicated in Figure 4B, the predetermined value used to indicate macrosomia may vary with the equation used.

Returning to step **ST24**, if the program determines that the rate of weight gain during the third trimester is not known, control proceeds to step **ST26** where the program determines whether biparietal diameter was measured at the last ultrasound. If the program determines that biparietal diameter was measured at the last ultrasound, control proceed to step **ST27** where the program determines whether the patient's weight at 182 days and the rate of weight gain during the third trimester are known. If both parameters are known, in step **ST28**, the program uses Equation 3 to predict risk of macrosomia. More particularly, if Equation 3 indicated that the predicted birth weight is greater than a predetermined value, such as 3850 grams, macrosomia is predicted.

Returning to step **ST27**, if only the patient's weight at 182 days is known, the program uses Equation 4 to predict risk of macrosomia (step **ST29**). Again,

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an exemplary prediction threshold value for Equation 4 of >3,800 grams is shown as an example of a cutoff for predicting macrosomia, but the scope of this invention is not intended to be limited to a particularly chosen predetermined cutoff value. If only the rate of gain during the third trimester is known, the program uses Equation 5 to predict macrosomia, using an exemplary cutoff value of >3,850 grams for predicting fetal macrosomia (step **ST30**). If neither parameter is known, control proceeds to step **ST31** where the program determines whether the fetal femur length (FL) was measured at the last ultrasound. If the fetal femur length (FL) was measured at the last ultrasound, control proceeds to steps **ST32** and **ST33** where the program determines whether maternal weight at 182 days and rate of weight gain during the third trimester are known. If both are known, in step **ST34**, the program uses Equation 7 to predict macrosomia, using an exemplary fetal weight threshold value of >3,810 grams. If only the patient's weight at 182 days is known, program uses Equation 8 to predict macrosomia, using an exemplary threshold value of >3,790 grams (step **ST35**). Returning to step **ST32**, if the maternal weight at 182 days is not known, control proceeds to step **ST36**, where the program determines that risk of macrosomia cannot be predicted.

Returning again to step **ST31**, if femur length was not measured at the last ultrasound, control proceeds to step **ST37** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known. If both are known, in step **ST38**, the program uses Equation 11 to predict macrosomia, using an exemplary threshold value of

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>3,800 grams. If only the patient's weight at 182 days is known, the program uses Equation 12 to predict macrosomia, using an exemplary threshold value of >3,780 grams (step **ST39**). If only the rate of weight gain during the third trimester is known, the program uses Equation 13 to predict macrosomia, using an exemplary threshold value of >3,810 grams (step **ST40**). Finally, if neither is known, the program determines that risk of macrosomia cannot be predicted.

Returning to step **ST22**, if the program determines that only the fetal head circumference (HC) was measured in the last ultrasound, control proceeds to step **ST41** where the program determines whether the patient's weight at 182 days and rate of weight gain during the third trimester are known.

If either or both of these parameters are unknown, control proceeds to step **ST23** where the program determines that macrosomia cannot be predicted. If both parameters are known, control proceeds to step **ST42** where the program determines whether the fetal biparietal diameter (BPD) was measured at the last ultrasound. If the fetal biparietal diameter (BPD) was measured at the last ultrasound, control proceeds to step **ST43** where the program predicts macrosomia using Equation 19, using an exemplary threshold value of >3,780 grams. If the fetal biparietal diameter (BPD) was not measured at the last ultrasound, control proceeds to step **ST44** where the program predicts macrosomia using Equation 23, using an exemplary threshold value of >3,760 grams.

Thus, as illustrated in Figures 4A and 4B, fetal birth weight/risk of macrosomia estimation software **110** can predict risk of macrosomia using a

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subset of the equations used to predict fetal birth weight. Predicting whether or not macrosomia will occur is useful in reducing health risks to both the mother and the unborn child.

In addition to producing binary output indicating whether or not macrosomia is suspected to exist on the specified target date, fetal birth weight/macrosomia risk estimation software 110 may also calculate and output percentages indicating the risk of macrosomia at birth. The following equations and the table that follows may be used by fetal birth weight/macrosomia risk estimation software 110 in predicting the risk of fetal macrosomia on the target date as a percentage in each case, depending upon which equation in the hierarchy of equations is used to calculate the risk of fetal macrosomia.

Probability of macrosomia (in %), given a predicted birth weight = $(\text{BaseProb} \times P_{\text{macro}}) \div [(100 - \text{BaseProb}) \times P_{\text{Nonmac}} + \text{BaseProb} \times P_{\text{Macro}}]$,

5 where

$P_{\text{macro}} =$ Probability that a macrosomic delivery will have the predicted birth weight = $\exp\{-0.5 \times [(Pred - M_{\text{Macro}}) \div SD_{\text{Macro}}]^2\} \div [SD_{\text{Macro}} \times \text{sqrt}(2\pi)]$

10

$P_{\text{nonmac}} =$ Probability that a non-macrosomic delivery will have the predicted birth weight = $\exp\{-0.5 \times [(Pred - M_{\text{Nonmac}}) \div SD_{\text{Nonmac}}]^2\} \div [SD_{\text{Nonmac}} \times \text{sqrt}(2\pi)]$

15

$Pred =$ The predicted birth weight, in grams

$M_{\text{Macro}} =$ The mean predicted birth weight for macrosomic deliveries, in grams

20

$M_{\text{Nonmac}} =$ The mean predicted birth weight for non-macrosomic deliveries, in grams

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SD_{Macro} = The standard deviation of the predicted birth weight for macrosomic deliveries, in grams

5 SD_{Nonmac} = The standard deviation of the predicted birth weight for non-macrosomic deliveries, in grams

and

10 BaseProb = Base rate of macrosomia (in %)
= 13% for Caucasians, 8% for African Americans, 7% for Filipinos, and 6% for Orientals

Values for M_{Macro} , SD_{Macro} , M_{Nonmac} , and SD_{Nonmac} vary with the prediction equation that is used to predict fetal macrosomia. These values, as presently known from empirical data, are indicated for each equation in Table 2 below.

Equation	M_{Macro}	SD_{Macro}	M_{Nonmac}	SD_{Nonmac}
1	3884	198	3403	356
3	3891	201	3389	344
4	3853	218	3394	336
5	3881	197	3401	349
7	3864	219	3387	338
8	3828	238	3392	330
11	3863	239	3385	330
12	3828	252	3390	324
13	3851	232	3385	324
19	3804	241	3410	307
23	3794	236	3409	303

Table 2: Macrosomia Risk Equation Variable Values

20 In Table 2, the stated values for the macrosomia risk equation variables

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are preferred values that have been obtained through empirical observation and experimentation. However, the present invention is not limited to using these exact values. Any suitable coefficients for obtaining accurate macrosomia risk predictions are intended to be within the scope of the invention.

Table 3 shown below illustrates the risks associated with macrosomia.

<u>Newborn and Maternal Complications Associated with Delivery of Fetuses</u>		
<u>Weighing >4,000 grams*</u>		
<u>Birth Weight >4,000 gm</u>		
<u>Complication</u>	<u>Relative Risk^a</u>	<u>Absolute Risk (%)</u>
Shoulder Dystocia	2.0-38	2-18%
Brachial Palsy	16-216	0.2-8%
Bony Injuries/ Fracture	1.4-97	0.2-7%
Prolonged Labor	2.2-3.2	4-19%
Birth Asphyxia/ Low Apgar Scores	1.7-5.6	1-14%
Forceps/Vacuum Extraction	1.5-3.6	11-39%
Birth Canal/Perineal Lacerations	1.6-5.1	3-11%
Postpartum Hemorrhage	1.6-5.2	4-6%
Cephalopelvic Disproportion	1.9-2.2	8-9%
Cesarean Section	1.2-2.9	13-39%

Table 3: Risks Associated with Macrosomia

* Data are compiled from 15 prior studies that have investigated both the relative risk and absolute risk of complications associated with the births of macrosomic fetuses. The ranges reflect differences among studies in the patient populations investigated as well as differences in the criteria used for the diagnosis of each complication.

^a Relative risks are for fetuses weighing >4,000 grams at delivery versus controls having birth weights of ≤4,000 grams; the p-value associated with each

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relative risk is $< .001$ in all cases, except for Birth Canal/ Perineal Lacerations, where the p-value is $< .05$.

5 All of the complications illustrated in Table 3 can be mitigated using the methods and systems for predicting fetal birth weight and risk of macrosomia described herein. For example, if fetal weight at birth and/or risk of macrosomia can be accurately predicted, preventative measures can be implemented that reduce the risk of harm to the child and to the mother. Since this invention permits the prediction of fetal weight at birth and the risk of fetal macrosomia as an ongoing function of gestational age, and since fetal weight
10 increases universally with advancing gestational age, this invention permits the option to inform obstetrical practitioners when they may intervene and effect delivery in advance of the fetus's weight exceeding the high-risk threshold of 4,000 grams, as well as when the risk of fetal macrosomia at a particular target delivery date exceeds any specified and/or predetermined unacceptable risk
15 percentage. Thus, the present invention is a significant advance in the field of pre-natal and intrapartum care.

Although the present invention has been described above with regard to steps performed by a computer program, the present invention is not limited to predicting birth weight or risk of macrosomia using a computer program. The equations and steps listed above can be performed manually without departing from the scope of the invention.

It will be understood that various details of the invention may be changed without departing from the scope of the invention. Furthermore, the foregoing description is for the purpose of illustration only, and not for the
20 purpose of limitation, as the invention is defined by the claims as set forth hereinafter.

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CLAIMS

What is claimed is:

1. A method for estimating fetal weight at birth, the method comprising:
 - (a) obtaining information concerning maternal characteristics for a fetus for which birth weight is to be estimated;
 - (b) obtaining information concerning ultrasonographically measured physical characteristics of the fetus; and
 - (c) estimating birth weight of the fetus based on the information concerning maternal characteristics and the information concerning ultrasonographically measured physical characteristics.
2. The method of claim 1 wherein obtaining information concerning maternal and ultrasonographically measured physical characteristics includes presenting a user with a questionnaire requesting the maternal and ultrasonographically measured physical characteristics.
3. The method of claim 2 wherein presenting a user with a questionnaire includes serving the questionnaire from a server to a client over a computer network.
4. The method of claim 2 wherein presenting the user with a questionnaire includes presenting the user with a questionnaire on a handheld computer.

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5. The method of claim 2 wherein presenting the user with a questionnaire includes presenting the user with a questionnaire on a personal computer.
6. The method of claim 2 wherein presenting the user with a questionnaire
5 includes presenting a user with software for execution on a computer associated with an ultrasound device.
7. The method of claim 2 wherein presenting the user with a questionnaire includes presenting the user with a questionnaire over the Internet.
8. The method of claim 1 wherein obtaining information concerning
10 maternal characteristics includes obtaining information regarding at least one of maternal race, expected due date, pre-pregnancy maternal weight, maternal weight during pregnancy, maternal illnesses, prior pregnancies, and altitude.
9. The method of claim 1 wherein obtaining information concerning
15 ultrasonographically measured physical characteristics includes obtaining information concerning fetal abdominal circumference, fetal head circumference, and fetal sex.
10. The method of claim 1 wherein obtaining information concerning
20 ultrasonographically measured physical characteristics includes determining the presence or absence of information concerning ultrasonographically measured physical characteristics and wherein estimating birth weight includes, in response to determining the absence

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of ultrasonographically measured physical characteristics, estimating birth weight based on maternal characteristics only.

11. The method of claim 1 wherein estimating birth weight includes selecting from a hierarchy of birth weight calculation equations based on the information obtained concerning maternal and ultrasonographically measured physical characteristics of the fetus.
12. The method of claim 1 wherein steps (a)-(c) are performed manually.
13. The method of claim 1 comprising obtaining information regarding paternal characteristics and wherein estimating birth weight of the fetus includes estimating birth weight based on the information regarding paternal characteristics in addition to the information concerning maternal and ultrasonographically measured physical characteristics.
14. The method of claim 1 comprising outputting a number on a computer display device, the number being the fetal birth weight estimate.
15. The method of claim 1 comprising outputting a range of birth weights with an associated degree of confidence.
16. The method of claim 1 comprising outputting an array of birth weights corresponding to an array of potential target dates of delivery.
17. The method of claim 1 comprising outputting an array of ranges of birth weights associated with a specified degree of confidence for an array of potential target dates of delivery.
18. A method for predicting risk of fetal macrosomia, the method comprising:

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- (a) obtaining information concerning maternal characteristics for a fetus for which risk of macrosomia is to be estimated;
 - (b) obtaining information concerning ultrasonographically measured physical characteristics of the fetus; and
 - 5 (c) estimating risk of macrosomia for the fetus based on the information concerning maternal characteristics and the information concerning ultrasonographically measured physical characteristics.
19. The method of claim 18 wherein obtaining information concerning
10 maternal and ultrasonographically measured physical characteristics includes presenting a user with a questionnaire requesting the maternal and ultrasonographically measured physical characteristics.
20. The method of claim 19 wherein presenting a user with a questionnaire includes serving the questionnaire from a server to a client over a
15 computer network.
21. The method of claim 19 wherein presenting the user with a questionnaire includes presenting the user with a questionnaire on a handheld computer.
22. The method of claim 19 wherein presenting the user with a
20 questionnaire includes presenting the user with a questionnaire on a personal computer.

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23. The method of claim 19 wherein presenting the user with a questionnaire includes presenting a user with software for execution on a computer associated with an ultrasound device.
24. The method of claim 19 wherein presenting the user with a questionnaire includes presenting a user with a user interface over the Internet.
25. The method of claim 18 wherein obtaining information concerning maternal characteristics includes obtaining information regarding at least one of maternal race, expected due date, pre-pregnancy maternal weight, maternal weight during pregnancy, maternal illnesses, prior pregnancies, and altitude.
26. The method of claim 18 wherein obtaining information concerning ultrasonographically measured physical characteristics includes obtaining information concerning maternal abdominal circumference, fetal head circumference, and fetal sex.
27. The method of claim 18 wherein obtaining information concerning ultrasonographically measured physical characteristics includes determining the presence or absence of information concerning ultrasonographically measured physical characteristics and wherein estimating fetal macrosomia includes, in response to determining the absence of ultrasonographically measured physical characteristics, estimating fetal macrosomia based on maternal characteristics only.

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28. The method of claim 18 wherein estimating risk of fetal macrosomia includes selecting from a hierarchy of birth weight calculation equations based on the information obtained concerning maternal and ultrasonographically measured physical characteristics of the fetus.
- 5 29. The method of claim 18 comprising performing steps (a)-(c) manually.
30. The method of claim 18 comprising obtaining information regarding paternal characteristics and wherein estimating risk of macrosomia of the fetus includes estimating risk of macrosomia based on the information regarding paternal characteristics in addition to the
- 10 information concerning maternal and ultrasonographically measured fetal physical characteristics.
31. The method of claim 18 comprising outputting on a computer display device, an indicator of the risk of macrosomia.
32. The method of claim 31 wherein the indicator represents the presence
- 15 or absence of macrosomia.
33. The method of claim 31 wherein the indicator represents a percentage risk of macrosomia.
34. A computer program product comprising computer-executable instructions embodied in a computer-readable medium for performing
- 20 steps comprising:
- (a) obtaining information concerning maternal characteristics for a fetus;

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- (b) obtaining information concerning ultrasonographically measured physical characteristics of the fetus; and
- (c) estimating at least one of birth weight, a range of birth weights, confidence intervals, and risk of macrosomia for the fetus based on the information concerning maternal characteristics and the information concerning ultrasonographically measured fetal physical characteristics.

35. The computer program product of claim 34 wherein obtaining information concerning maternal and ultrasonographically measured physical characteristics includes presenting a user with a questionnaire requesting the maternal and ultrasonographically measured physical characteristics.

36. The computer program product of claim 35 wherein presenting a user with a questionnaire includes serving the questionnaire from a server to a client over a computer network.

37. The computer program product of claim 35 wherein presenting the user with a questionnaire includes presenting the user with a questionnaire on a handheld computer.

38. The computer program product of claim 35 wherein presenting the user with a questionnaire includes presenting the user with a questionnaire on a personal computer.

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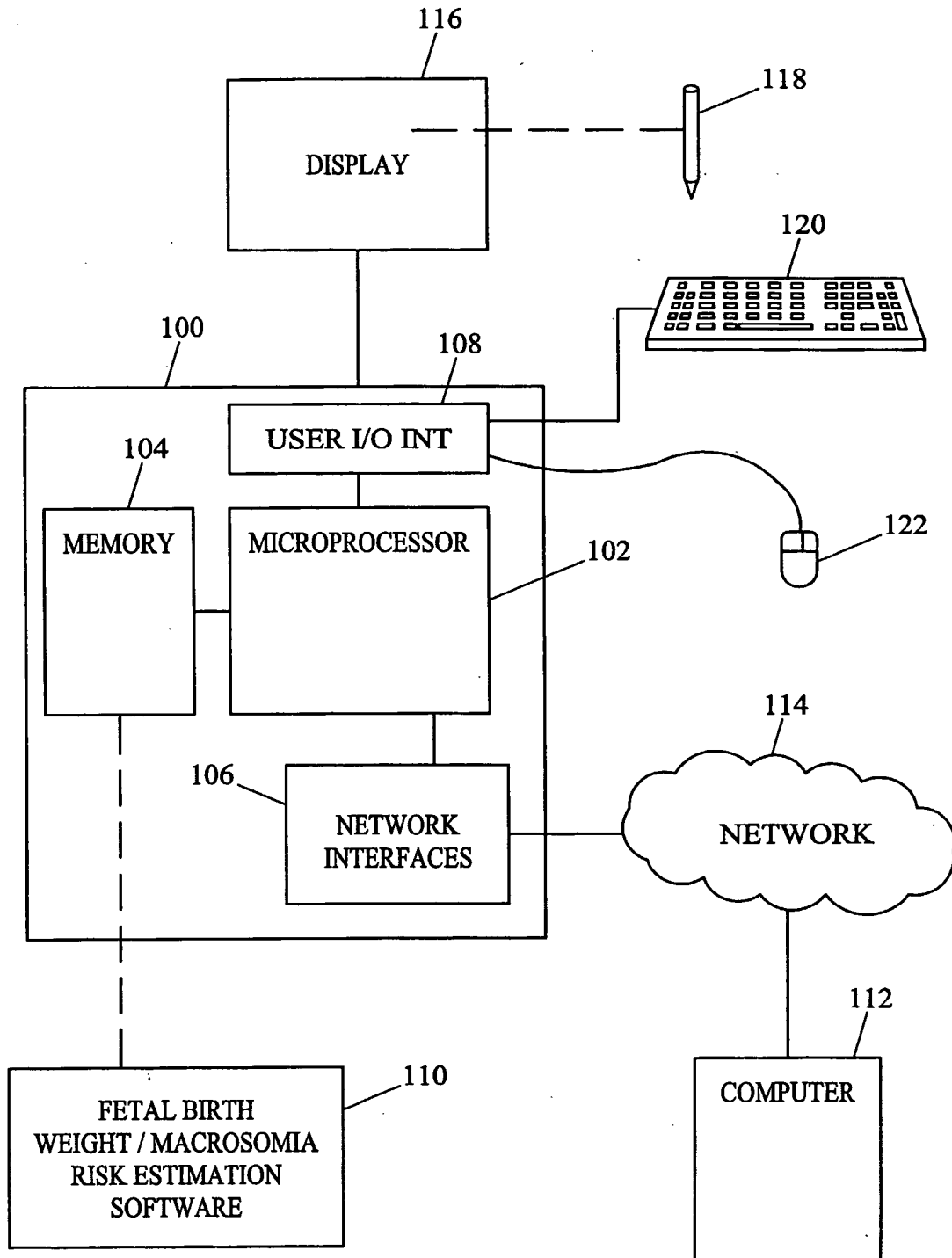
39. The computer program product of claim 35 wherein presenting the user with a questionnaire includes presenting a user with software for execution on a computer associated with an ultrasound device.
40. The computer program product of claim 35 wherein presenting the user with a questionnaire includes presenting the user with a user interface over the Internet.
41. The computer program product of claim 34 wherein obtaining information concerning maternal characteristics includes obtaining information regarding at least one of maternal race, expected due date, pre-pregnancy maternal weight, maternal weight during pregnancy, maternal illnesses, prior pregnancies, and altitude.
42. The computer program product of claim 34 wherein obtaining information concerning ultrasonographically measured physical characteristics includes obtaining information concerning maternal abdominal circumference, fetal head circumference, and fetal sex.
43. The computer program product of claim 34 wherein obtaining information concerning ultrasonographically measured physical characteristics includes determining the presence or absence of information concerning ultrasonographically measured physical characteristics and wherein estimating birth weight includes, in response to determining the absence of ultrasonographically measured physical characteristics, estimating birth weight based on maternal characteristics only.

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44. The computer program product of claim 34 wherein estimating birth weight includes selecting from a hierarchy of birth weight calculation equations based on the information obtained concerning maternal characteristics and ultrasonographically measured physical characteristics of the fetus.
45. The computer program product of claim 34 wherein estimating birth weight of a fetus includes estimating birth weight with an accuracy of at least about 8.5%.
46. The computer program product of claim 34 comprising obtaining information regarding paternal characteristics and wherein estimating birth weight of the fetus includes estimating birth weight based on the information regarding paternal characteristics in addition to the information concerning maternal and ultrasonographically measured physical characteristics.
47. The computer program product of claim 34 comprising outputting a number on a computer display device, the number being the fetal birth weight estimate.
48. The computer program product claim 34 comprising outputting on a computer display device, an indicator of the risk of macrosomia.
49. The computer program product of claim 48 wherein the indicator represents the presence or absence of macrosomia.
50. The computer program product claim 48 wherein the indicator represents a percentage risk of macrosomia.

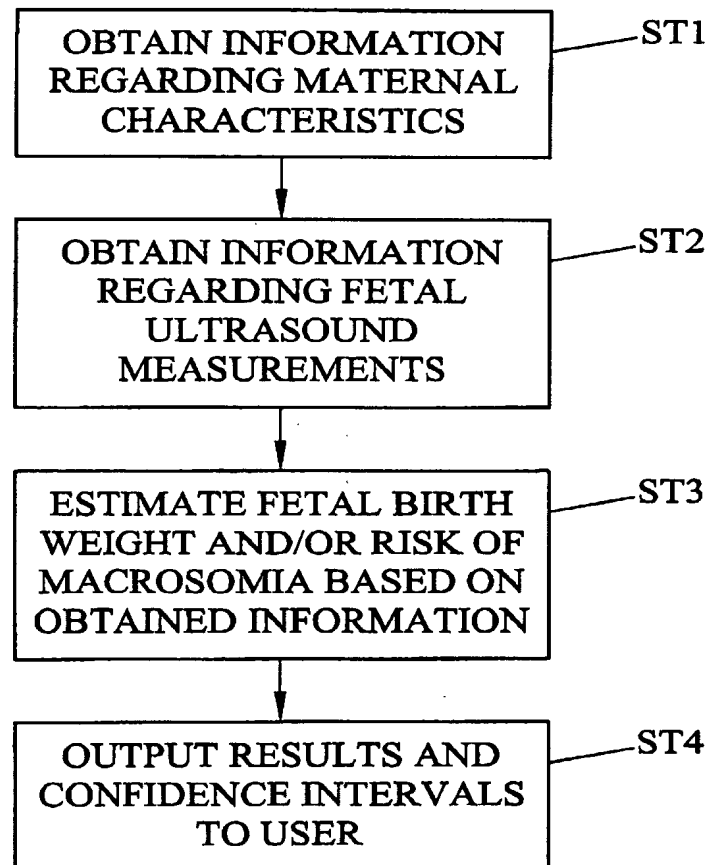
1/11

FIG. 1



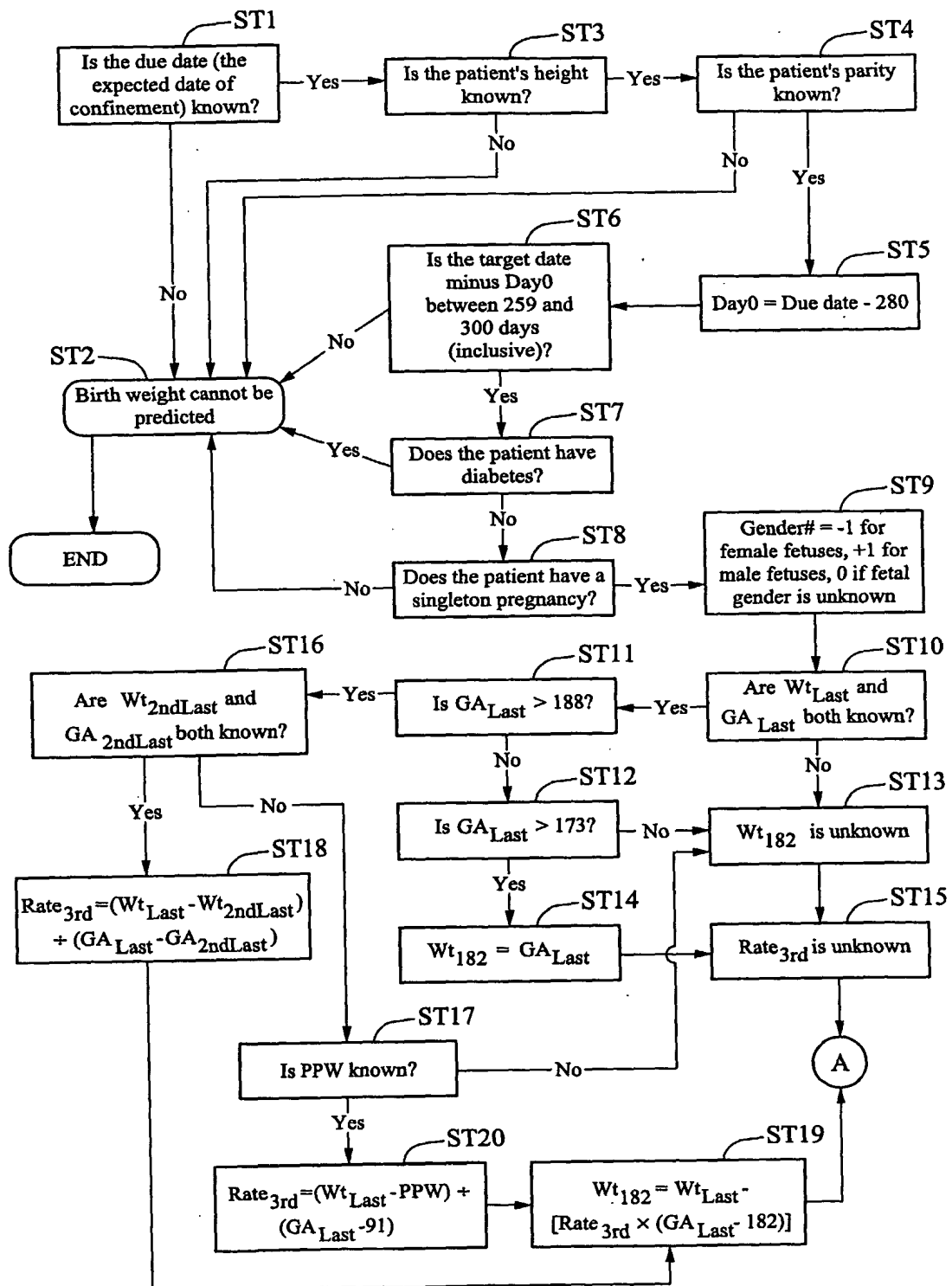
2/11

FIG. 2



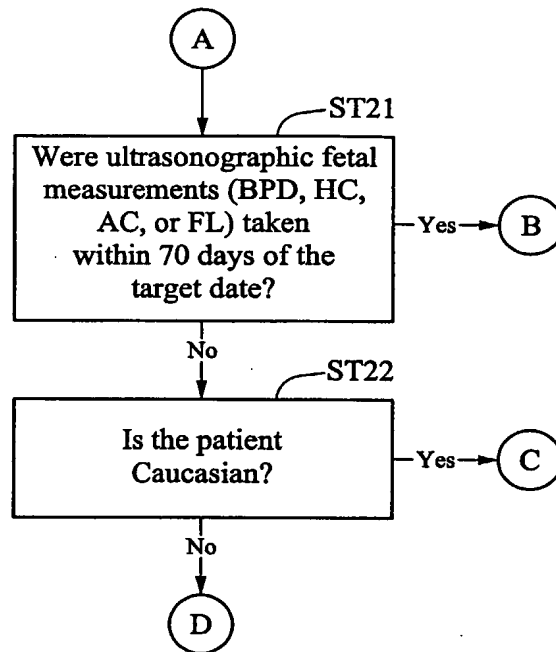
3/11

FIG. 3A



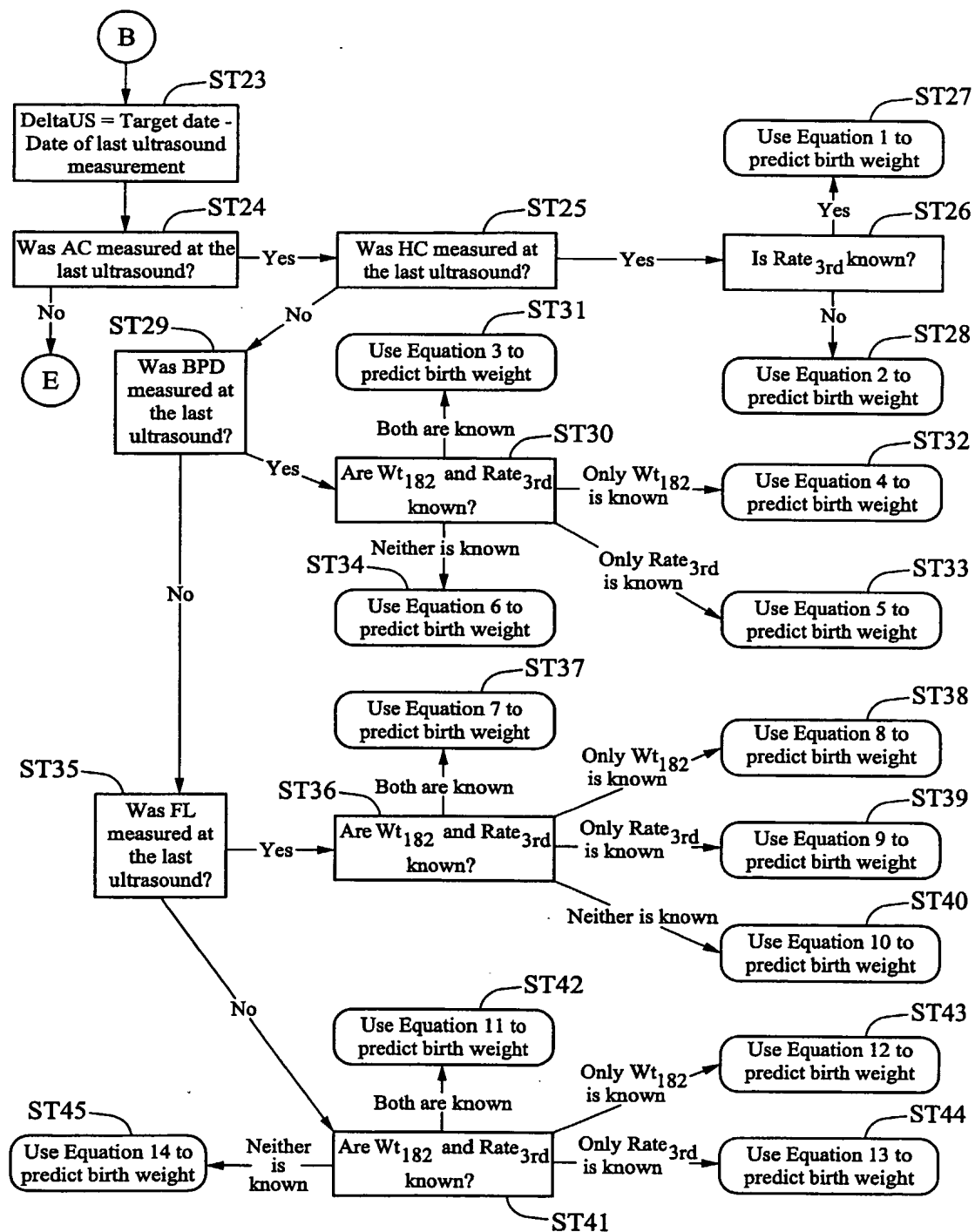
4/11

FIG. 3B



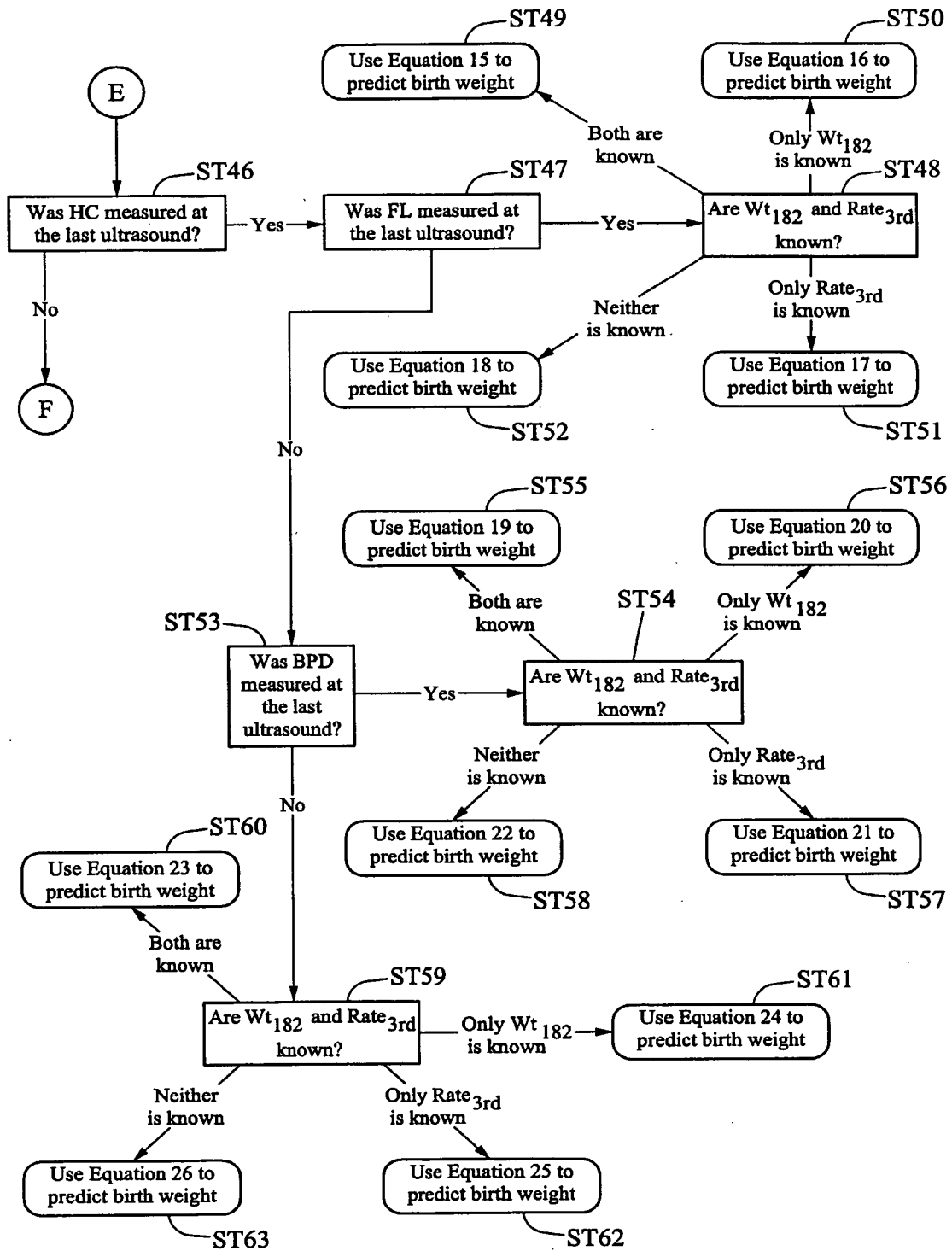
5/11

FIG. 3C



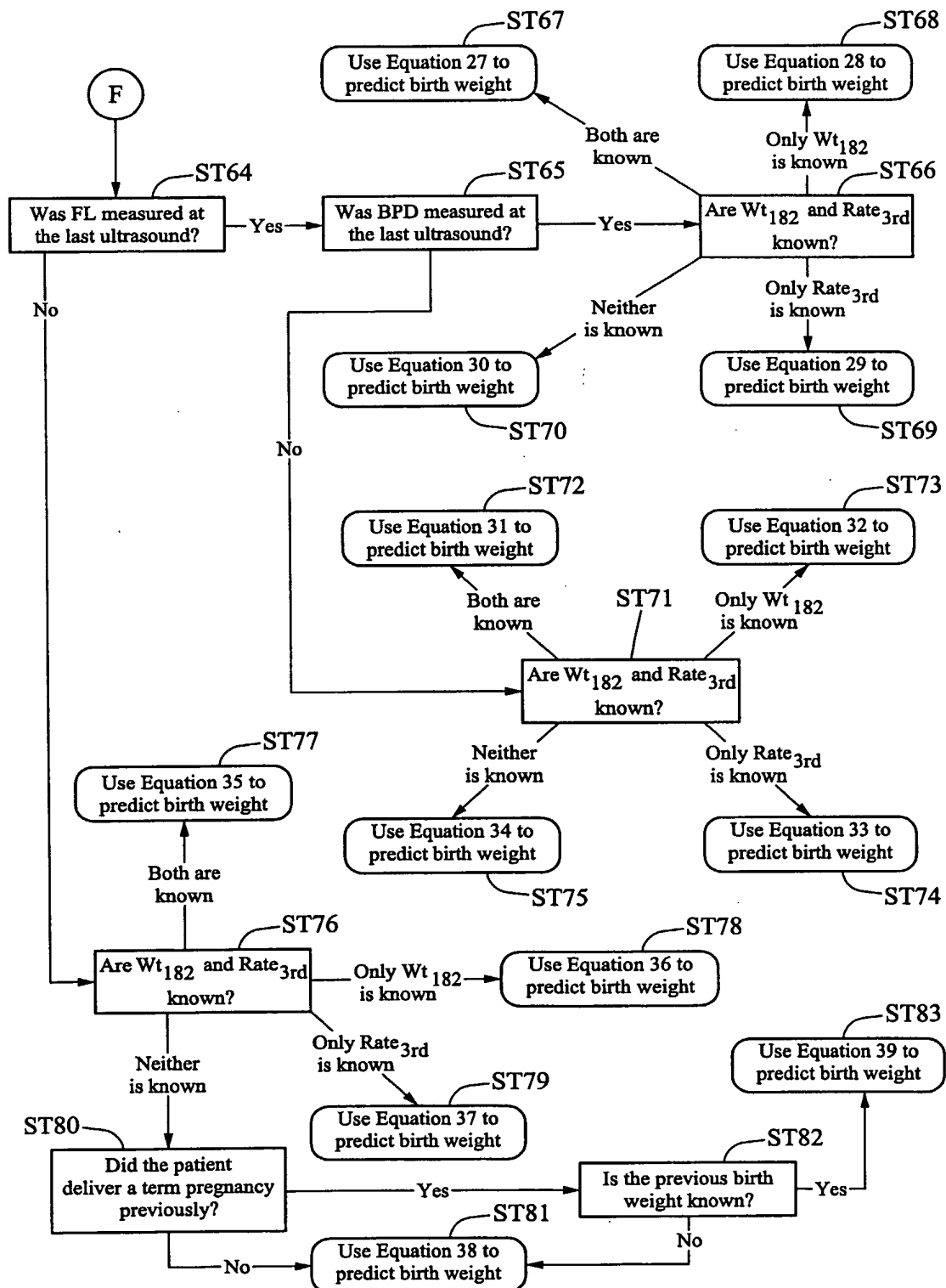
6/11

FIG. 3D



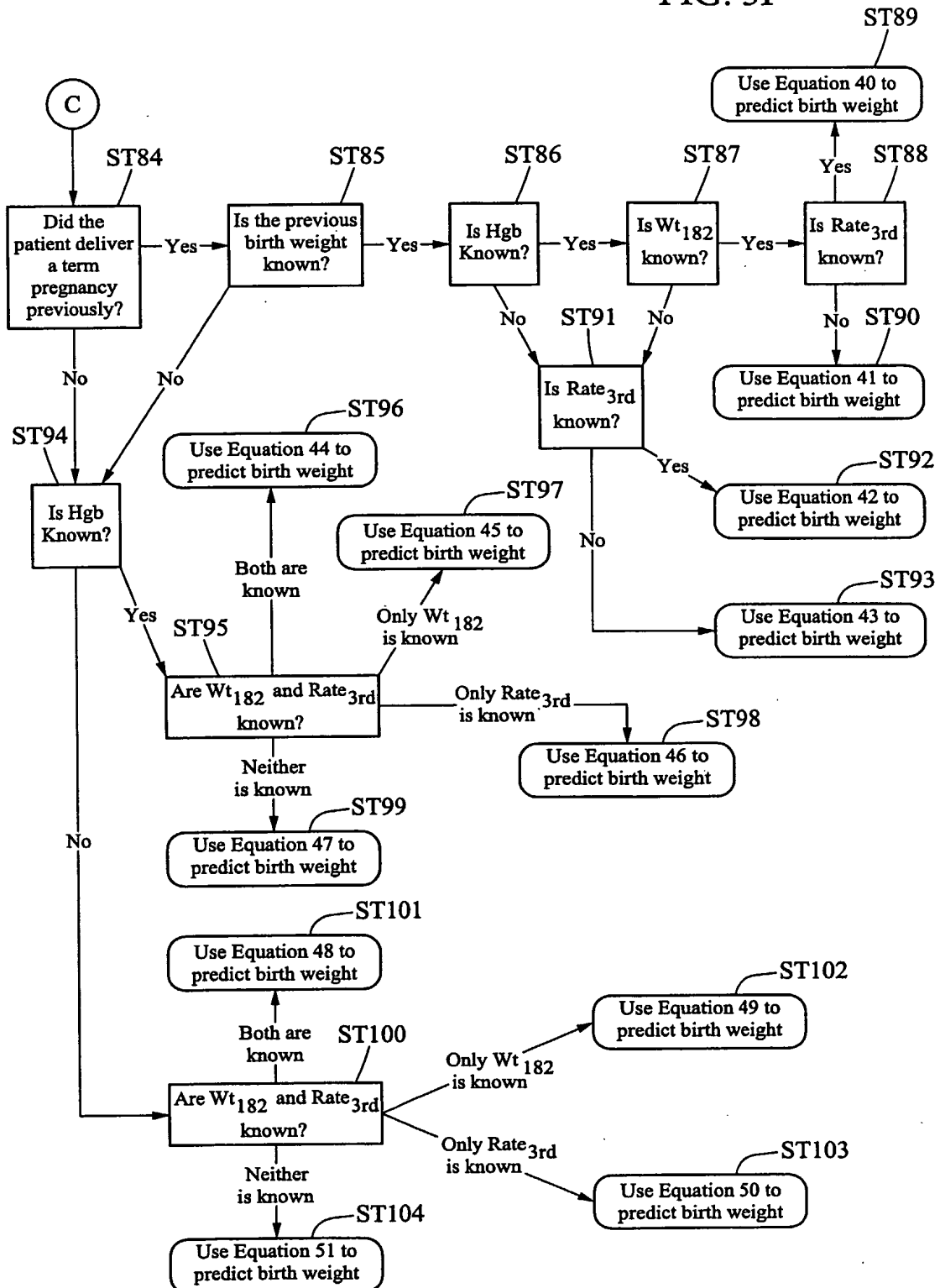
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FIG. 3E



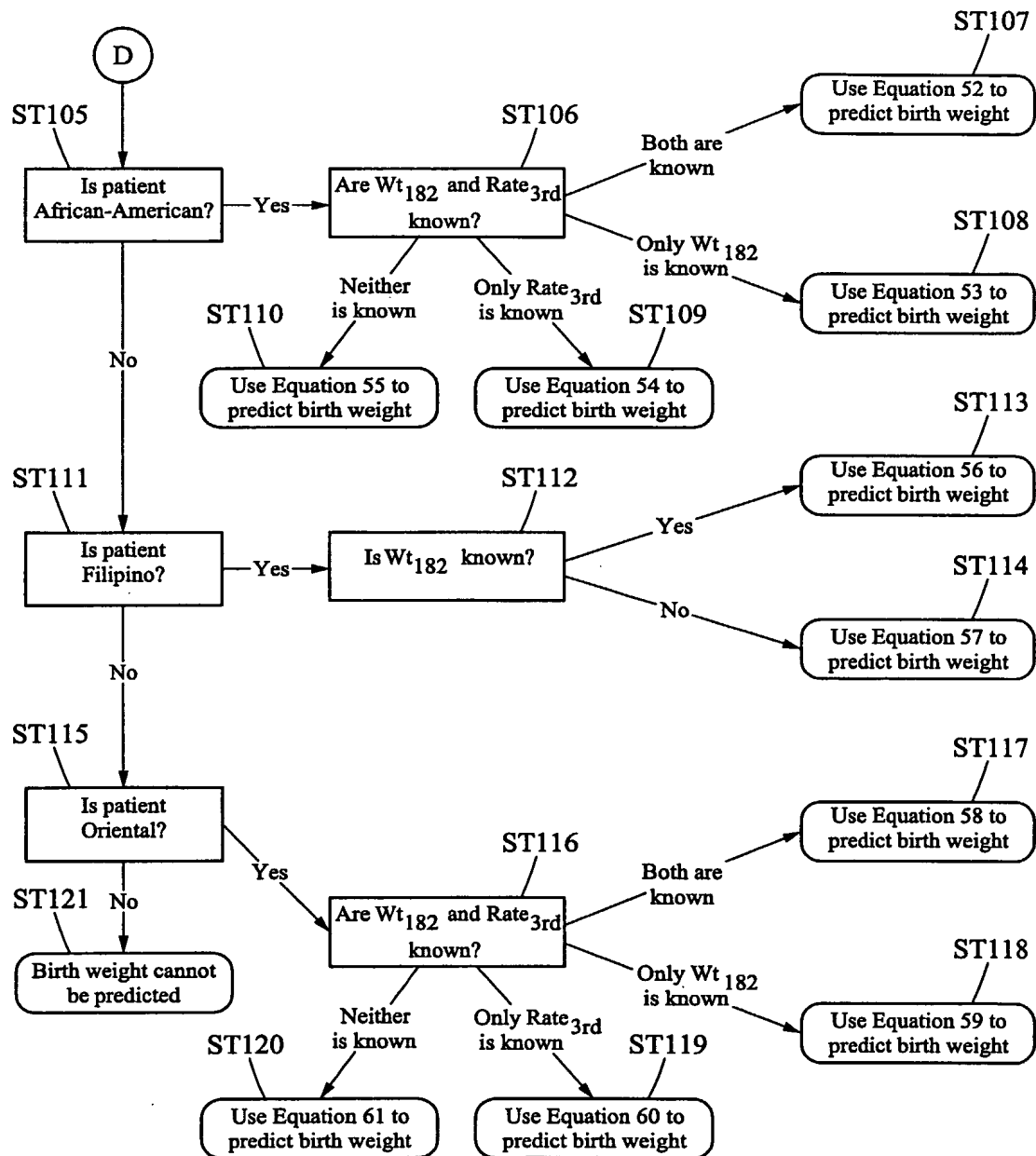
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FIG. 3F



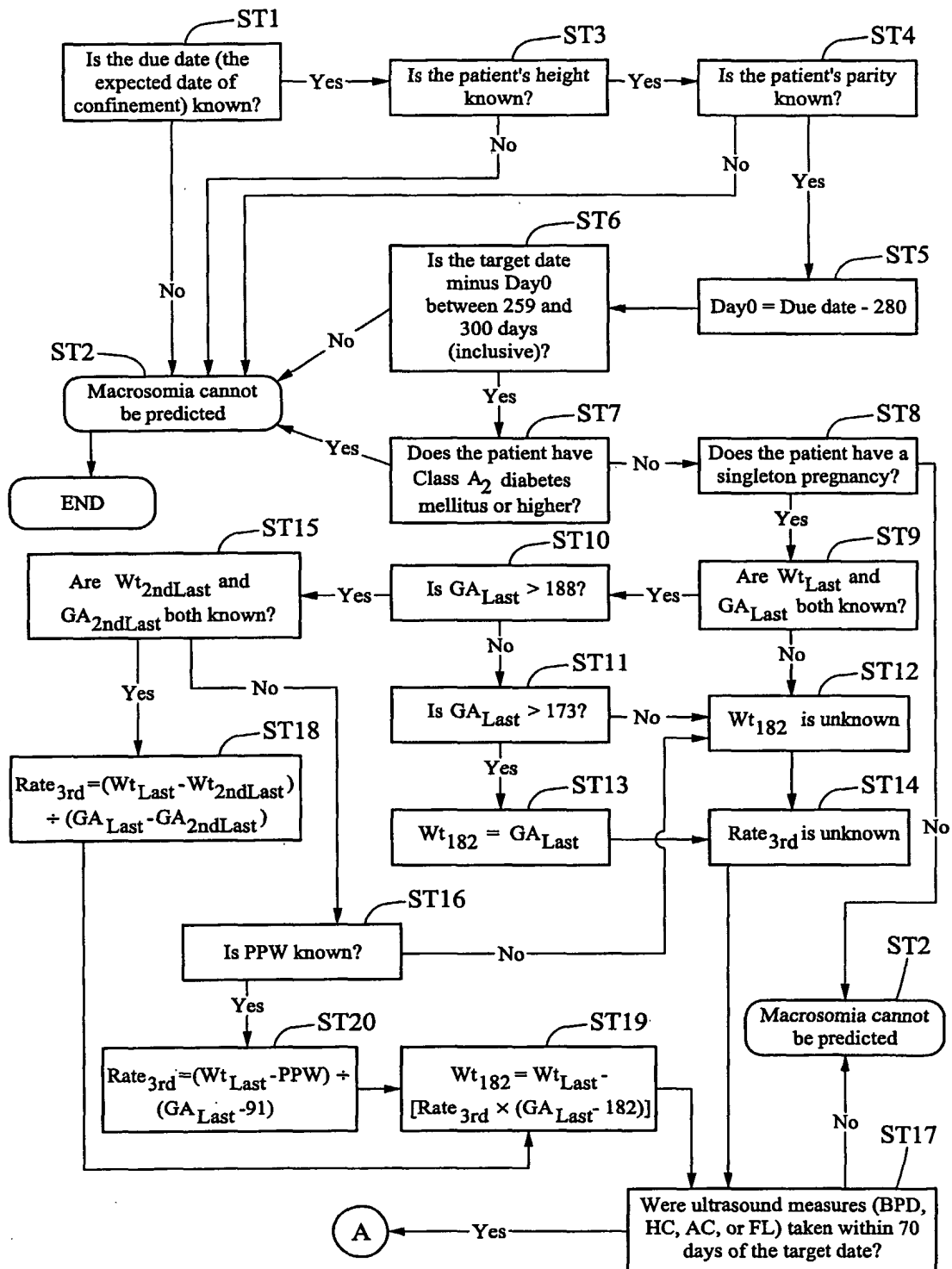
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FIG. 3G



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FIG. 4A



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FIG. 4B

